IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK & CO., INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 06-230 (GMS)
	)	
APOTEX, INC.	)	**JURY TRIAL DEMANDED**
	)	
Defendant.	)	

APOTEX INC.'S REPLY IN SUPPORT OF ITS MOTION FOR LEAVE TO FILE ITS FIRST AMENDED ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS

Richard L. Horwitz (#2246)
Kenneth L. Dorsney (#3726)
POTTER ANDERSON & CORROON LLP
Hercules Plaza, 6th Floor
1313 N. Market Street
P. O. Box 951
Wilmington, DE 19899
Tel: (302) 984-6000
rhorwitz@potteranderson.com
kdorsney@potteranderson.com

Attorneys for Defendant Apotex, Inc.

OF COUNSEL:

A. Sidney Katz
Robert B. Breisblatt
Louise T. Walsh
Michael Krol
Welsh & Katz, Ltd.
120 S. Riverside Plaza, 22nd Floor
Chicago, Illinois 60606
Tel: (312) 655-1500
Fax: (312) 655-1501

Dated: December 8, 2006

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Other Authorities

Rules

Regulations

INTRODUCTION

In its answering brief in opposition to Defendant Apotex, Inc.'s ("Defendant's" or "Apotex's") motion for leave to file a First Amended Answer, Affirmative Defenses, and Counterclaims ("First Amended Answer"), Plaintiff Merck & Co., Inc. ("Plaintiff" or "Merck") contends that the amendment should not be allowed because Apotex's proposed affirmative defense is moot and the proposed antitrust counterclaim is futile because it fails to adequately allege an antitrust claim under Fed. R. Civ. P. 12(b)(6). In essence, Merck's opposition is a 12(b)(6) motion directed at Apotex's antitrust counterclaim. Merck, however, cannot satisfy the high standard required to dismiss the antitrust counterclaim at the pleadings stage. Moreover, Merck raises a myriad of factual issues that are not contained in Apotex's proposed amended counterclaim, and therefore should not be considered on a Rule 12(b)(6) motion. Because Apotex has adequately alleged its antitrust counterclaim, the amendment is not futile and leave to amend should be granted.

ARGUMENT

I. THE STANDARD FOR AMENDMENT UNDER RULE 15(a)

Merck opposes Apotex's amendment on the grounds of futility in that the antitrust counterclaim allegedly fails to state a claim under Rule 12(b)(6). A claim may be dismissed under Rule 12(b)(6) only if it appears beyond doubt that Apotex could prove no set of facts in support of the claim that would entitle it to relief. *See Conley v. Gibson*, 355 U.S. 41, 45-46, 78 S. Ct. 99 (1957). In considering such a motion, a court must accept all of the facts alleged in the complaint as true and must liberally construe the complaint in the light most favorable to Apotex. *See ALA, Inc. v. CCAIR, Inc.*, 29 F.3d

855, 859 (3rd Cir. 1994); *Scheuer v. Rhodes*, 416 U.S. 232, 236, 94 S. Ct. 1683, 1686 (1974). The question is not whether the plaintiff will prevail, but whether he is entitled to present evidence in support of his claims. *See Scheuer*, 416 U.S. at 236

The dismissal standard is even higher in antitrust cases than it is generally. *See Rolite, Inc. v. Wheelabrator Envtl. Sys., Inc.*, 958 F. Supp. 992, 995 (E.D. Pa. 1997); *Hosp. Bldg. Co. v. Trs. of Rex Hosp.*, 425 U.S. 738, 746, 96 S. Ct. 1848 (1976) ("[I]n antitrust cases…dismissals prior to giving the plaintiff ample opportunity for discovery should be granted very sparingly."); *Commonwealth of Pa. ex rel. Zimmerman v. PepsiCo, Inc.*, 836 F.2d 173, 179 (3rd Cir. 1988) ("[W]e should be extremely liberal in construing antitrust complaints.").

In ruling on a 12(b)(6) motion to dismiss, a court may consider only the counterclaim, exhibits attached to the counterclaim (in this case, none), matters of public record, and undisputedly authentic documents if the counterclaims are based upon those documents. *See Pension Benefit Guar. Corp. v. White Consol., Indus.*, 998 F.2d 1192, 1196 (3rd Cir. 1993).

In light of the liberal pleading philosophy of the Federal Rules and this Court's responsibility to examine the complaint to determine if the allegations provide for relief on any possible theory, while construing the complaint in the light most favorable to Apotex, Merck has not satisfied its burden under Rule 12(b)(6).

II. APOTEX'S PROPOSED ANTITRUST COUNTERCLAIM IS NOT FUTILE

Merck's arguments that Apotex's proposed antitrust counterclaim is futile fail because: (1) Apotex is suffering antitrust injury because of the 30-month stay; (2) Apotex will suffer antitrust injury because of the 180-day exclusivity period; (3) Apotex can

establish injury-in-fact; and (4) Apotex has alleged facts sufficient to overcome *Noerr-Pennington* immunity.

A. Apotex Has Adequately Pled Facts Establishing Antitrust Standing

The Third Circuit employs a five-factor test for antitrust standing. *See In re Warfarin Sodium Antitrust Litig.*, 214 F.3d 395, 399 (3rd Cir. 2000) (citing *Associated Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters*, 459 U.S. 519, 535-46, 103 S. Ct. 897 (1983)). Merck argues that the second factor, which requires that the plaintiff's alleged injury is of the type that the antitrust laws were intended to redress (otherwise knows as "antitrust injury"), is not satisfied. Merck is wrong.

1. Apotex Suffers Injury from the 30-Month Stay

a. Under A Plain Reading Of The Statute, The 30-Month Stay Will Not Be Lifted Automatically Upon Entry Of Dismissal

Merck contends that Apotex will not be injured by the 30-month stay because the 30-month stay will terminate following a dismissal with prejudice based upon Merck's covenant not to sue. Merck relies principally on the language of the statute itself,[1] 21 U.S.C. § 355(j)(5)(B)(iii)(I) (2003), specifically the parenthetical referring to a "substantive determination that there is no cause of action for patent infringement or invalidity."[2] As noted by Merck, there is no authority interpreting the language in the

---

[1] *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279, 1289 (S.D. Fla. 2005) is not persuasive because the court's passing reference to a dismissal lifting the 30-month stay was pure dicta.

[2] The parenthetical in the statute was added as a result of the Medicare Amendments Act in 2003. *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub.L. No. 108-173, § 1101(a)(2)(A)(ii), 117 Stat. 2066 (amended 2003) (hereinafter "MMA"). Previously, the statute provided, in relevant part, that: "approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the [paragraph IV] notice…except that (I) if before the expiration of such period the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of the court decision…" 21 U.S.C. § 355(j)(5)(B)(iii) (2002).

parenthetical. However, Merck's argument that this language would include a dismissal for lack of subject matter jurisdiction based upon a plain reading of the statute is erroneous.

Merck's interpretation of the language in the parenthetical fails to recognize the distinction between a court's power to hear the case, *i.e.*, its subject matter jurisdiction, and the merits of a case. A court may have subject matter jurisdiction even where a complaint fails to state a cause of action and vice versa. As the Supreme Court has explained:

> Jurisdiction…is not defeated…by the possibility that the averments might fail to state a cause of action on which petitioners could actually recover. For it is well settled that the failure to state a proper cause of action calls for a judgment on the merits and not a dismissal for want of jurisdiction. Whether the complaint states a cause of action on which relief could be granted is a question of law and just as issues of fact it must be decided after and not before the court has assumed jurisdiction over the controversy. If the court does later exercise its jurisdiction to determine that the allegations in the complaint do not state a ground for relief, then dismissal of the case would be on the merits, not for want of jurisdiction.

Bell v. Hood, 327 U.S. 678, 682, 66 S. Ct. 773 (1946); *see also Steel Co. v. Citizens For A Better Env't*, 523 U.S. 83, 89, 118 S. Ct. 1003 (1998) ("It is firmly established in our cases that the absence of a valid (as opposed to arguable) cause of action does not implicate subject-matter jurisdiction, *i.e.*, the court's statutory or constitutional *power* to adjudicate the case.") (emphasis in original).

The legal insufficiency of a federal claim generally does not eliminate the subject matter jurisdiction of a federal court. *See Growth Horizons, Inc. v. Delaware County*, 983 F.2d 1277, 1280 (3rd Cir. 1993); *City of Philadelphia v. Beretta U.S.A. Corp.*, 277 F.3d 415, 419 n. 3 (3rd Cir. 2002) (City had standing under Article III but there was no cause of action and case was dismissed under Rule 12(b)(6)); *Kulick v. Pocono Downs Racing*

Ass'n, Inc., 816 F.2d 895, 899 (3rd Cir. 1987) ("dismissal for lack of jurisdiction is not appropriate merely because the legal theory alleged is probably false"). Conversely, dismissal for lack of subject matter jurisdiction is distinct from determining whether a cause of action has been stated. *See City of Philadelphia*, 277 F.3d at 419 n. 3 (specifying that action was being dismissed as to the organizational plaintiffs under Rule 12(b)(1) for lack of standing, not on the merits under Rule 12(b)(6)).

Thus, a "substantive determination that there is no cause of action for patent infringement or invalidity" is a decision directed at the merits, either by way of summary judgment or failure to state a claim. It would not include a dismissal for lack of subject matter jurisdiction, which is what Merck's motion sought. (D.I. 15) *See Miller v. U.S. Postal Serv.*, 729 F.2d 1033, 1035 n. 4 (5th Cir. 1984) (dismissal for lack of subject matter jurisdiction was not a decision on the merits and therefore not res judicata). Accordingly, a dismissal for lack of subject matter jurisdiction would not constitute a "substantive determination that there is no cause of action for patent infringement or invalidity" and therefore, would not terminate the 30-month stay under 21 U.S.C. § 355(j)(5)(B)(iii)(I).

Merck cites no authority for its contention that a dismissal for lack of subject matter jurisdiction is *ipso facto* a determination that Apotex does not have a cause of action for patent invalidity or infringement. (*See* Merck's Brief at p. 15.) Merck is wrong in conflating the two. There is a difference between a dismissal on the merits and a dismissal for want of jurisdiction. *See Growth Horizons*, 983 F.2d at 1280-81; *Nesbit v. Gears Unlimited, Inc.*, 347 F.3d 72, 76-80 (3rd Cir. 2003) (discussing distinction between substantive elements of a claim and subject matter jurisdiction); *Johnsrud v. Carter*, 620 F.2d 29, 31-33 (3rd Cir. 1980) (district court erred in dismissing the complaint for lack of

subject matter jurisdiction because it failed to state a claim); *Wheeldin v. Wheeler*, 373 U.S. 647, 649, 83 S. Ct. 1441 (1963) (court recognized that the plaintiff did not state a cognizable Fourth Amendment claim but, nevertheless, concluded that the district court erred in dismissing the complaint for lack of subject matter jurisdiction).[3]

Merck also argues, contrary to the plain meaning of the statute, that the FDA's policy is to lift the 30-month stay upon a dismissal of a patent infringement suit, and that Apotex knows this based upon the FDA's approval of Apotex's generic version of Zaditor® after a lawsuit brought by the brand name drug company, Novartis Pharmaceuticals Corp. ("Novartis"), was dismissed.

First, if Merck is correct that Apotex's contentions regarding the effect of a dismissal on the 30-month stay is a legal conclusion (*see* Merck's Brief at p. 13), then Merck cannot rely upon factual matters, especially factual matters outside of Apotex's pleading. Whether the FDA in fact approved one of Apotex's ANDA applications prior to the expiration of the 30-month stay is irrelevant to the motion at hand because it is not in

[3] Merck attempts to tread a fine line in offering to have the Court's dismissal order recite that the Court has determined that due to the covenant that Merck provided to Apotex, Merck does not have a cause of action for patent infringement against Apotex, and Apotex does not have a cause of action for patent invalidity against Merck. (*See* Merck's Brief at p. 15.) Merck is willing to accede to a termination of the 30-month stay, but without triggering the 180-day exclusivity period of the first to file. Merck knows that the FDA recently construed the "court decision" trigger for the 180-day exclusivity period very strictly as requiring an actual "holding" on the merits that the patent is invalid, not infringed, or unenforceable. *See* Letter from Gary Buehler, Dir., Office of Generic Drugs, to Pravastin ANDA applicant, dated April 11, 2006, at pp. 1-2 ("Buehler Letter") (Ex. A hereto); *see also Apotex, Inc. v. FDA*, 449 F.3d 1249 (D.C. Cir. 2006) (upholding the FDA's interpretation). Moreover, the FDA made clear that the holding must be clear on the face of the document. *See Buehler Letter*, at p. 2. Thus, a court decision with a finding that there is no "cause of action" for patent invalidity or infringement probably would not be acceptable to the FDA for purposes of triggering the 180-day exclusivity period. Apotex's refusal to agree to Merck's proposed dismissal order does not mean that Merck's interpretation of the language in the parenthetical is correct; it only means that Apotex is concerned that the FDA may not agree that a finding that there is no "cause of action" constitutes a "court decision" triggering event for the 180-day exclusivity period because of the rigid position the FDA has taken in construing a "court decision" triggering event.

any pleading. If, on the other hand, Apotex's contentions are issues of fact, then Apotex's allegations must be taken as true for purposes of Merck's 12(b)(6) motion. Merck cannot have it both ways. The facts asserted by Merck merely create factual disputes which this Court should not resolve on a 12(b)(6) motion. *See Lee v. City of Los Angeles*, 250 F.3d 668, 688 (9th Cir. 2001) ("factual challenges to a plaintiff's complaint have no bearing on the legal sufficiency of the allegations under Rule 12(b)(6)"); *Tal v. Hogan*, 453 F.3d 1244, 1265-66 (10th Cir. 2006) (declining to consider public records that would have contradicted allegation in complaint; "Rule 12(b)(6) motions to dismiss are not designed to weigh evidence or consider the truth or falsity of an adequately pled complaint.").

Second, even if Merck were correct that the FDA approved one of Apotex's ANDA applications where a patent infringement action had been dismissed prior to the expiration of the 30-month stay, this one incident is not enough to establish the FDA's policy, nor the FDA's policy going forward. Under Fed. R. Evid. 201, a court may only take judicial notice of a fact that is 'not subject to reasonable dispute." Fed. R. Evid. 201(b). While the Court has authority under Rule 201 to take judicial notice of the *fact* that Novartis filed a complaint against Apotex, the *fact* that the case was dismissed, and the *fact* that the FDA approved Apotex's ANDA for ketotifen fumarate, the Court may not infer the meaning of the statute from those facts, nor may it infer the FDA's policy with respect to the language in the statute, to the extent that the FDA's policy is relevant. *See Lee*, 250 F.3d at 689-90 (district court erred in taking judicial notice of disputed facts and failing to draw all reasonable inferences in plaintiff's favor).

There is nothing in the FDA's own regulations that would suggest a policy of granting approvals when a case is dismissed prior to the expiration of the 30-month stay.

Indeed, the FDA's current regulation provides that: "If before the expiration of the 30-month period…the court issues a final order that the patent is invalid, unenforceable, or not infringed, approval may be made effective on the date the court enters judgment." 21 C.F.R. § 314.107(b)(3)(ii).[4] If it is, or was, the FDA's policy to approve ANDA applications prior to the expiration of the 30-month stay when a case is dismissed without a court decision on invalidity or noninfringement, that policy does not appear as though it would have been in compliance with the statute, either the current post-MMA version or the prior verion. "If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Chevron, U.S.A. Inc. v. NRDC*, 467 U.S. 837, 842-43, 104 S. Ct. 2778 (1984).

If the FDA's policy had been challenged, or if it is challenged, a court might well find that the FDA's interpretation of the statute is incorrect. *See Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1076 (D.C. Cir. 1998) (finding that the FDA exceeded its statutory authority in imposing the "successful defense" requirement as a prerequisite to the invocation of the 180-day exclusivity rule by a first applicant under section

---

[4] The FDA considered, but withdrew, a rule that explicitly would have terminated the 30-month stay if the case was dismissed without a court decision on the merits. The FDA's proposed rule § 314.107(g) provided in relevant part:

> (g) *Effect of dismissal of litigation on 30-month stay.* If the patent litigation between the ANDA applicant and the patent owner or NDA holder described in paragraph (b)(3)(A) of this section is dismissed without a court decision on the merits of the patent claim, whether the dismissal is with or without prejudice, the agency may immediately approve the ANDA that was the subject of the litigation, if it is otherwise eligible for approval.

180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications, 64 Fed. Reg. 42873, 42886 (1999) (to be codified at 21 C.F.R. pt. 314) (proposed Aug. 6, 1999). On November 1, 2002, however, the FDA withdrew the proposed rule published on August 6, 1999, without commenting on the provision regarding the effect of dismissal on the 30-month stay. *See* 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications, 67 Fed. Reg. 66593 (2002) (to be codified at 21 C.F.R. pt. 314) (withdrawal of proposed rule).

355(j)(5)(B)(iv)); *Ranbaxy Labs. Ltd. v. Leavitt*, 2006 WL 3289050, at *5 (D.C. Cir. Nov. 14, 2006) (holding unlawful the FDA's policy requiring the first filer of a paragraph IV certification be sued in order to preserve its statutory exclusivity when the NDA holder seeks to delist the patent rather than to litigate) (Ex. B hereto).

Finally, given the FDA's recent interpretation of the "court decision" trigger for the 180-day exclusivity, and the D.C. Circuit's upholding of that interpretation, *see Apotex*, 449 F.3d at 1251-52, along with the similarity of the "court decision" language in both the 30-month stay provision and the 180-day exclusivity provision, there is no guarantee that the FDA would approve ANDA applications where the patent infringement lawsuit was dismissed prior to the expiration of the 30-month stay going forward.

b. The Court's Authority To Shorten The 30-Month Stay Is Limited To Certain Circumstances That Do Not Apply Here

Merck also argues that the Court can shorten the 30-month stay and offers to agree to an order explicitly dispensing with the 30-month stay upon dismissal. First, Merck's shortening suggestion presents issues of fact, which this Court should not consider in a 12(b)(6) motion. The Court should not glean facts from Merck's arguments on a 12(b)(6) motion. *See In re Warfarin Sodium Litig.*, 214 F.3d at 398 (district court improperly considered matters outside the pleadings on a 12(b)(6) motion to dismiss).

Second, Merck's assertion that the Court may shorten the 30-month stay in the circumstances here presented may not be correct. The statute merely provides that the period may be adjusted "because either party to the action failed to reasonably cooperate in expediting the action." 21 U.S.C. § 355(j)(5)(B)(iii). For example, in *Dey, L.P. v. Eon Labs, Inc.*, 2005 U.S. Dist. LEXIS 39475, at *11-12 (C.D. Cal. Dec. 22, 2005) (Ex. C

hereto), the case relied upon by Merck, the court shortened the 30-month stay because the plaintiff's failure to form a clear position on inventorship at the beginning of the action, as reflected by its repeated changes of position on the issue, was unreasonable and would likely delay the case. On the other hand, in *Andrx Pharmaceuticals, Inc. v. Biovail Corp.*, 276 F.3d 1368, 1376 (Fed. Cir. 2002), the Federal Circuit held that the district court exceeded its authority in shortening the 30-month stay because of allegedly improper conduct before the FDA since the statute addresses only delay related to the particular infringement action. Thus, a district court's power to shorten the 30-month stay is not without limits. Whether Merck's presentation of its covenant not to sue in an attempt to avoid an adverse decision on the merits would constitute a "fail[ure] to reasonably cooperate in expediting the action" is not known.

Third, Merck's gesture is ineffective because it would not address both causes of injury faced by Apotex. FDA approval of Apotex's ANDA for alendronate sodium is being blocked not only by the 30-month stay but also by the 180-day exclusivity of the first to file. If Merck is successful in delaying the first filer's entry beyond February 6, 2008, the bottleneck caused by the 180-day exclusivity could easily extend beyond the expiration of the 30-month stay. Merck knows this; and knows that by agreeing to dispense with the 30-month stay, it gives up nothing.

2. Apotex Suffers Injury from Being Unable To Trigger The 180-Day Exclusivity Period

Merck contends that Apotex's claimed injury of delayed entry into the U.S. market for alendronate sodium is not an antitrust injury because the delay is being caused by the Hatch-Waxman Act, rather than conduct by Merck. Merck is wrong.

First, it is well-established that exclusion of a competitor from a market constitutes antitrust injury. *See Biovail Corp. Int. v. Hoechst Aktiengesellschaft*, 49 F. Supp. 2d 750, 772 (D.N.J. 1999) ("The injury alleged—the intentional attempt to exclude competitors from the market and maintain monopoly power—is precisely the type of injury that the antitrust laws were intended to prevent."); *Abbott Labs. v. Teva Pharms. USA, Inc.*, 432 F. Supp. 2d 408, 431 (D. Del. 2006) (allegation that generic drug company was excluded from the market for a certain drug, or delayed market entry, was adequate to allege antitrust injury).

Moreover, Apotex's preclusion from the market is directly caused by Merck's conduct. A plaintiff need only show that a violation is a "material cause" of the claimed injury, not the "exclusive" cause. *See In re Wellbutrin SR/Zyban Antitrust Litig.*, 281 F. Supp. 2d 751, 756 (E.D. Pa. 2003) (citing *Zenith Radio Corp. v. Hazeltine Research*, 395 U.S. 100, 114 n. 9, 89 S. Ct. 1562 (1969)); *Rossi v. Standard Roofing, Inc.*, 156 F.3d 452, 483 (3rd Cir. 1998) (plaintiff must show illegal conduct was a material cause of its injury); *Danny Kresky Enters. Corp. v. Magid*, 716 F.2d 206, 211 (3rd Cir. 1983) ("the standard of causation requires only that plaintiff prove that defendant's illegal conduct was a material cause of its injury").

In *In re Wellbutrin*, the district court rejected defendants' argument that there was no causal connection between the alleged illegal conduct (defendants' filing of frivolous lawsuits for the purpose of triggering the 30-month stay) and the alleged injury, *i.e.*, the unavailability of generic Wellbutrin SR. *In re Wellbutrin SR/Zyban Antitrust Litig.*, 281 F. Supp. 2d at 755-56. While a generic drug company's failure to enter the market could have been caused by requirements of the FDA and the Hatch-Waxman Act, it was also

possible that defendants' frivolous lawsuits and the resulting burdensome patent litigation created the obstacle to the generic drug companies' entry into the market. *Id.* at 757. The court would therefore not dismiss the case on a 12(b)(6) motion. *See also Warner Lambert Co. v. Purepac Pharm. Co.*, 2000 WL 34213890, at *8 (D.N.J. Dec. 22, 2000) (brand manufacturer's institution of suit against generic manufacturer, which thereby delayed FDA approval of generic form and hence delayed generic entry into the market, was sufficient causation to allege antitrust injury) (Ex. D hereto).

Relying primarily on *City of Pittsburgh v. West Penn Power Co.*, 147 F.3d 256 (3rd Cir. 1998), Merck argues that Apotex lacks standing because its claimed injury is not due to any conduct by Merck, but rather because of the regulatory scheme under the Hatch-Waxman Act. As the district court explained in *In re K-Dur Antitrust Litig.*, 338 F. Supp. 2d 517, 535 (D.N.J. 2004), *City of Pittsburgh* is distinguishable.

In *City of Pittsburgh*, the City of Pittsburgh brought antitrust claims against two utility companies, one that sought authorization to provide power to the City and one that was an existing authorized power provider, because their merger reduced competition. *See City of Pittsburgh*, 147 F.3d at 262. The Third Circuit found that the plaintiff's antitrust injuries were overly speculative and lacked the proper causal connection because a "regulatory scheme…interfere[d] with the chain of causation." *Id.* at 268. The regulatory scheme in *City of Pittsburgh* did not provide for, nor specifically encourage competition. The causal link was broken because the statute prohibited the parties from being competitors in the first place. *Id.* at 267. The regulatory scheme in *City of Pittsburgh* was an independent cause which fully accounted for the plaintiff's alleged

antitrust injury. *See In re Cardizem Antitrust Litig.*, 105 F. Supp. 2d 618, 652-53 (E.D. Mich. 2000).

Here, the Hatch-Waxman scheme does not fully account for Apotex's injury. Apotex would not be barred by the 180-day exclusivity period but for the fact that Merck listed patents in the Orange Book. Moreover, the Hatch-Waxman Act does not prevent competition between the parties, but is, in fact, intended to promote competition between brand and generic manufacturers. *See In re K-Dur*, 338 F. Supp. 2d at 535. Whereas, in *City of Pittsburgh*, it was the structure of the regulated industry that created the lack of competition. *See City of Pittsburgh*, 147 F.3d at 269.

In *K-Dur*, the plaintiffs alleged that agreements in which a brand name drug manufacturer made payments to two generic drug manufacturers, including the first generic filer, in exchange for their delayed entry into the market violated antitrust laws. *See In re K-Dur*, 338 F. Supp. 2d at 526. The plaintiffs alleged that the collusion between the brand name and generic manufacturers eliminates generic entry into the market because the 180-day exclusivity period enjoyed by the first to file will not run until the first filer enters the market, thus keeping prices high and injuring the plaintiffs. *Id.* The district court found such allegations sufficient to cause antitrust injury. *Id.* at 535. "If the 180-day period is manipulated or abused through an agreement between the brand and generic manufacturers, then this will cause injury to flow from the agreement." *Id.*

In a similar case, the D.C. Circuit disagreed with the district court's conclusion that the alleged injury suffered by the secondary generic manufacturer was caused not by the agreement between the brand name drug manufacturer and the first generic applicant but instead by the lack of FDA approval and the statutory scheme of the Hatch-Waxman

Act. *See Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 808-09 (D.C. Cir. 2001). The appellate court concluded that it was sufficient that the first generic applicant's "commitment not to trigger the running of the 180-day exclusivity period could have caused [the secondary generic's] injury…by denying it the ability to proceed to market with its own generic." *Id.* at 810. "Although the 180-day provision of the Hatch-Waxman Amendments legally barred it from selling its product, [the first generic's] manipulation of the exclusivity period trigger date extended the legal bar." *Id.*[5]

In the present case, Apotex has alleged that Merck is manipulating the 180-day exclusivity period by filing baseless lawsuits and then presenting sham covenants not to sue in order to avoid a "court decision" triggering event, which would enable Apotex and other secondary generic manufacturers to enter the market. (Countercl.[6] ¶¶ 74, 98, 116, 128, 130.) Just like the agreements in *K-Dur* and *Andrx*, Merck's manipulation of the 180-day exclusivity period is causing direct injury to Apotex.[7]

---

[5] Merck's reliance on *Bristol-Myers Squibb Co. v. Copley Pharmaceutical, Inc.*, 144 F. Supp. 2d 21, 23-25 (D. Mass. 2000) is misplaced because the court in *Bristol-Myers Squibb* relied in part on *Andrx Pharmaceuticals, Inc. v. Friedman*, 83 F. Supp. 2d 179 (D.D.C. 2000) for its finding regarding lack of causation. However, the D.C. Circuit disagreed with the district court's conclusion in *Andrx Pharm. v. Friedman* that the injury was caused by "the existence of a troublesome regulatory scheme" rather than the agreement between the brand and first generic. *See Andrx Pharm. v. Biovail*, 256 F.3d at 808-09, *reversing in part Andrx Pharm. v. Friedman*, 83 F. Supp. 2d 179 (D.D.C. 2000).

[6] "Countercl." refers to the counterclaim in Apotex's First Amended Answer.

[7] *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2nd Cir. 2006) is distinguishable in at least two very significant ways. One, in the settlement agreement with the brand manufacturer, Barr, the first generic filer, agreed to change its ANDA from a paragraph IV certification to a paragraph III certification. *Id.* at 193-94. Two, the district court upheld the validity of the patent at issue in each of the cases against the secondary generic filers. *Id.* at 195. Thus, the plaintiffs could not have suffered any antitrust injury with regard to the exclusivity period for Barr from the time of the settlement agreement until the FDA changed its regulations to remove the "successful defense" requirement because secondary generics were not being blocked by the 180-day exclusivity period since Barr had changed to a paragraph III certification. *Id.* at 219-220. After the regulations changed and Barr tried to recapture its 180-day exclusivity period, the plaintiffs could not have suffered any antitrust injury because the secondary generic filers had already lost their infringement suits against the brand manufacturer and so could not have entered the market

Merck would like to forget the fact that it was the one that first brought suit against Apotex. By presenting Apotex with a covenant not to sue, attempting to dismiss this case, and now even offering to agree to a court order attempting to terminate the 30-month stay, Merck contends that Apotex is in no different position than it would have been in had Merck not sued. Such an argument should be rejected. As one court noted, "denying injury when the plaintiff is no worse off than he would have been in the absence of any violation does not mean...that the defendant should prevail merely by asserting what he *would otherwise have done.*" *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d at 652 (quoting 2 P. Areeda & H. Hovenkamp, *Antitrust Law* ¶ 363c at 225 (Rev. ed. 1997)) (emphasis in original).

Merck cannot transform the facts of this case into the facts of *Teva Pharmaceuticals USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324 (Fed. Cir. 2005), *reh'g and reh'g en banc denied*, 405 F.3d 990 (Fed. Cir. 2005), *and cert. denied*, 126 S. Ct. 473 (2005), and expect this Court to dismiss this case for the same reasons that case was dismissed. It did sue Apotex first, and it presented Apotex with a covenant not to sue precisely to avoid an adverse decision on the merits. This case is not *Teva v. Pfizer*. Instead, this case is more like *Minnesota Mining and Manufacturing Co. v. Barr Laboratories, Inc.*, 289 F.3d 775, 780 (Fed. Cir. 2002), where the court would not allow the plaintiff to manipulate the court's jurisdiction by seeking a dismissal without

---

due to the brand manufacturer's valid patent. *Id.* at 200. Thus, the injury suffered by the plaintiffs from lack of generic competition was due to the brand manufacturer's patent monopoly, which remained valid until its expiration. *Id.* In the case at bar, Apotex is being blocked by the 180-day exclusivity of the first generic filer, rather than Merck's patent monopoly since Merck's patents have not been held valid by a court, nor has Apotex been found to have infringed any of Merck's patents.

prejudice in order to avoid what the plaintiff apparently thought would have been a triggering event of the first filer's 180-day exclusivity period.

Furthermore, *Teva v. Pfizer* was not an antitrust case. In *Teva v. Pfizer*, the brand name drug company (Pfizer) failed to file an infringement action against the generic drug company (Teva) in response to the generic drug company's paragraph IV certification. Teva then filed a declaratory judgment action in order to obtain a "court decision" triggering event. Teva's lawsuit was dismissed for lack of subject matter jurisdiction because there was no "reasonable apprehension" of patent litigation under the Federal Circuit's two-part test for determining whether there is an "actual controversy" under the Declaratory Judgment Act, 28 U.S.C. §2201(a). *See Teva v. Pfizer*, 395 F.3d at 1334. The Court further found that the Medicare Amendments did not alter the requirement of the Federal Circuit's two-part test. *Id.* at 1337.

With respect to the discussion on injury for Article III standing, the Federal Circuit found that Teva did not suffer injury-in-fact because there was no wrongful conduct by Pfizer. *See Teva v. Pfizer*, 395 F.3d at 1338 ("The injury about which Teva complains is the product of the Hatch-Waxman scheme *and the fact that Pfizer has acted in a manner permitted under that scheme*.") (emphasis added). Pfizer merely listed its patents in the Orange Book as it was required to do. *Id.* at 1333. Pfizer did not sue Teva; nor did it attempt to dismiss the case based on a covenant not to sue Teva.

In the present case, there is wrongful conduct by Merck that, coupled with the Hatch-Waxman scheme, results in injury to Apotex. Merck filed its lawsuit against Apotex knowing Apotex did not infringe any valid claims of Merck's patents, and then presented Apotex with a sham covenant not to sue in order to avoid an adverse decision

on the merits that would have terminated the 30-month stay and triggered the 180-day exclusivity period of the first generic filer. (Countercl. ¶¶ 115-116.) Thus, Merck's filing of this lawsuit, and the covenant not to sue, have directly injured Apotex by delaying its entry into the market. These facts distinguish this case from *Teva v. Pfizer*.[8]

Moreover, Apotex is not "required" by the Hatch-Waxman Act to wait for the company that was first to file a paragraph IV certification to begin selling its generic product, as Merck contends. (*See* Merck's Brief at p. 24.) There is nothing in the Hatch-Waxman scheme that prohibits a secondary generic from triggering the 180-day exclusivity period prior to when the first generic filer(s) is able to enter the market. To the contrary, it is well established that the "court decision" triggering event can be generated in a lawsuit with any generic filer, not just the first generic filer. *See SmithKline Beecham Corp. v. Geneva Pharms., Inc.*, 210 F.R.D. 547, 554 (E.D. Pa. 2002) (denying first generic filer's attempt to intervene in case to prevent court decision that might have triggered its 180-day exclusivity before it could enter the market; "it is clear that [the first generic filer's] exclusivity period can be triggered by the termination of an action commenced by a subsequent applicant"); *3M*, 289 F.3d at 780; *Teva Pharms., USA, Inc. v. FDA*, 182 F.3d 1003, 1005 n. 3 (D.D.C. 1999) ("As interpreted by the FDA, the statute does not guarantee the first ANDA applicant a 180-day period of exclusivity. The court-decision trigger can be activated by any subsequent ANDA applicant's

[8] Similarly, Merck's reliance on *Apotex, Inc. v. FDA*, 449 F.3d 1249 (D.C. Cir. 2006) is misplaced. In *Apotex v. FDA*, the court was asked to review the FDA's decision construing a "court decision" sufficient to trigger the 180-day exclusivity period. As in *Teva v. Pfizer*, the plaintiff was a secondary generic manufacturer who had filed a declaratory judgment action to obtain a "court decision" trigger of the first filer's 180-day exclusivity period. *Id.* at 1251. Whether a generic manufacturer can maintain a suit under the Declaratory Judgment Act against a patent holder who has promised never to sue for patent infringement, and whether the generic manufacturer suffers injury if not allowed to maintain such an action, is not at issue in the case at bar.

litigation whether or not the first applicant has enjoyed a period of exclusivity."); *Mova Pharms. Corp.*, 140 F.3d at 1073 (suggesting use of declaratory judgment action as means for subsequent ANDA applicant to trigger exclusivity period).

If Congress wanted to protect the first generic filer's 180-day exclusivity period from being triggered in a different action before the first generic could utilize the exclusivity period, it certainly could have amended the statute to do just that. It has not, and Apotex has every right to a decision on the merits that, if in Apotex's favor, would constitute a triggering event of the first generic filer's 180-day exclusivity period. Allowing Apotex to enter the market in this way is consistent with the overall purpose of the Hatch-Waxman Amendments, *i.e.*, to make it easier for generic drugs to enter the market by allowing challenges to invalid and non-infringed patents that would otherwise block the public's access to generic drugs.

3. Apotex Has Suffered Injury-In-Fact

Merck argues that Apotex has not suffered injury-in-fact because the alleged injury is too remote and speculative, specifically, in that: (1) Apotex has not yet received FDA approval to market its generic version of alendronate sodium, and (2) its claims that Merck's patents are invalid or not infringed are too speculative. Merck is wrong on both counts.

Apotex is injured by Merck's anti-competitive acts because its entry into the market will be delayed. *See Andrx Pharms.*, 256 F.3d at 806 ("When competitors violate the antitrust laws and another competitor is forced from a market, the latter suffers an injury-in-fact."). Apotex has alleged that if Merck had not presented its covenant not to sue, Apotex would have obtained a "court decision" finding the patents invalid or not

infringed, which would have terminated the 30-month stay and triggered the first generic filer's 180-day exclusivity period, thereby allowing Apotex to enter the market in February 2008. (Countercl. ¶ 74, 115-117.) The 30-month stay prevents Apotex from entering the market until at least August 24, 2008. (Countercl. ¶ 51.) The 180-day exclusivity period prevents Apotex from entering the market until 180 days after the first filer enters, which can be no sooner than February 6, 2008, but may be later.[9] (Countercl. ¶¶ 18, 19, 81, 82.) At the very least, delayed entry into the market constitutes a threat of injury even if not actual injury at this time.

In this action, Apotex seeks damages and injunctive relief under the antitrust laws. *See* 15 U.S.C. § 15, 26. When seeking injunctive relief under the antitrust laws, a party need not allege actual antitrust injury, but only the *threat* of antitrust injury. *See* 15 U.S.C. § 26; *Weiss v. York Hosp.*, 745 F.2d 786, 829 (3rd Cir. 1984); *Biovail*, 49 F. Supp. 2d at 772-73 (district court indicated it was not "troubled" by the fact that plaintiff had not in fact been injured by defendants' conduct foreclosing plaintiff from market because plaintiff was seeking injunctive relief where only the threat of antitrust injury is

[9] Merck is wrong that FDA approval and the "court decision" must all occur prior to February 5, 2008 for Apotex to suffer any injury. (*See* Merck's Brief at p. 30.) The first filer, allegedly Teva Pharmaceuticals USA, Inc. ("Teva") (*see* Countercl. ¶ 81), might not enter the market on February 6, 2008 even though it may have received FDA approval to do so. Merck is currently engaged in actions specifically designed to delay Teva's entry into the market. In addition to having attempted to overturn a previous court decision that found two claims of the '329 patent invalid by charging Teva with fraud (*see* Countercl. ¶¶ 83-87), Merck has brought a suit in the United States International Trade Commission against Teva's potential supplier of alendronate sodium for infringement of a process patent owned by Merck and has filed a declaratory judgment action against Teva for infringement of the same patent. (*See* Apotex's Reply In Support Of Its Motion For Leave to File Surreply at pp. 8-9, D.I. 31.) If Merck's actions against Teva are successful, Teva's entry into the market may be delayed substantially beyond February 2008. Alternatively, Merck and Teva may settle their litigation which may include an agreement that Teva not enter the market until well beyond February 2008. Thus, there are a number of possible scenarios in which the "court decision" triggering event and FDA approval could happen after February 5, 2008 and still provide benefit to Apotex by triggering Apotex's entry into the market.

required); *In re Warfarin Sodium Antitrust Litig.*, 214 F.3d at 399 ("injunctive relief under section 16 [of the Clayton Act, 15 U.S.C. § 26] only requires a threat of loss"); *City of Pittsburgh,* 147 F.3d at 264 ("when seeking injunctive relief, the complainant need only demonstrate a significant threat of injury from an impending violation of the antitrust laws."); *cf. City of Los Angeles v. Lyons*, 461 U.S. 95, 105-106, 103 S. Ct. 1660 (1983) (for standing, a plaintiff who seeks injunctive relief must show that the defendant's conduct will likely cause injury in the future). Thus, to the extent that Apotex's injury allegations reflect only a threat of injury in that its entry into the market will be delayed beyond February 6, 2008 by Merck's illegal conduct, such allegations do not fail to state an antitrust injury.

a. Apotex Has Sufficiently Alleged That It is Prepared To Enter The Market For Alendronate Sodium

Apotex has alleged that it produces more than 260 generic pharmaceuticals sold throughout the world, including a generic form of 70 mg alendronate sodium in Canada. (Countercl. ¶¶ 109, 111.) It alleged that it has expended considerable effort and resources to develop a generic version of alendronate sodium that is therapeutically equivalent or bio-equivalent to Merck's Fosamax. (Countercl. ¶ 110.) Apotex further alleged that it has taken all actions necessary to obtain FDA approval of its ANDA for alendronate sodium, and that the FDA will likely grant tentative approval of its ANDA once the FDA's review is completed. (Countercl. ¶¶ 112, 113.) Additionally, Apotex alleged that the FDA will grant final approval once the 30-month stay is terminated and the 180-day exclusivity period of the first to file expires. (Countercl. ¶ 113.) Upon receiving final FDA approval, Apotex alleges that it intends to, and is prepared to, enter the U.S. market for generic alendronate sodium. (Countercl. ¶ 114.) These allegations are sufficient to show Apotex's

intent and preparedness to enter the market for alendronate sodium. *See Andrx Pharms.*, 256 F.3d at 808 (indicating that a party "could have alleged its intent and preparedness to enter the market by claiming that FDA approval was probable").

Merck's argument fails to recognize the reality of Hatch-Waxman.[10] In a classic patent infringement case, a patentee may sue an alleged infringer only when the defendant actually enters the market. Thus, doctrines of antitrust standing require that a competitor be prepared to enter the market before bringing an antitrust claim. *See Indium Corp. of Am. v. Semi-Alloys, Inc.*, 781 F.2d 879, 882 (Fed. Cir. 1985). In contrast, under Hatch-Waxman, a patentee may sue a generic drug company when it submits an ANDA, before it ever enters the market. As one court explained in connection with an argument identical to Merck's:

> Were the court to accept Bristol's position, antitrust standing under the Hatch-Waxman Act would be wholly contingent on the vagaries of the timing of agency action. If the FDA acted immediately to grant conditional approval to an ANDA, the generic applicant would have standing to bring antitrust claims. But if, as here, the patentee beat the applicant to the punch by filing a motion to dismiss before FDA approval, the generic maker would be denied antitrust standing. Such an anomalous and arbitrary result was not intended by the statute.

---

[10] Merck's reliance on *Joint Stock Soc'y v. UDV N. Am., Inc.*, 53 F. Supp. 2d 692, 702-05 (D. Del. 1999) and *Joint Stock Soc'y v. UDV N. Am., Inc.*, 266 F.3d 164, 176 (3rd Cir. 2001) is misplaced since *Joint Stock Soc'y* was not a Hatch-Waxman case. In *Joint Stock Soc'y*, the plaintiff, a Russian distiller, brought an action for, *inter alia*, trademark cancellation against an American distiller over the trademark SMIRNOFF. The plaintiff wanted to use the mark SMIRNOV for vodka and essentially sought an opinion from the court as to whether that mark would infringe the defendants' SMIRNOFF mark for vodka. 53 F. Supp. 2d at 701-702. The district court found that there was no justiciable case or controversy because the plaintiff had not meaningfully or adequately prepared to begin selling their SMIRNOV vodka in the United States. *Id.* at 701. Among other things, the plaintiffs had no business or marketing plan, had not undertaken any advertising, and had not even sought government approval for entry into the U.S. market. *Id.* at 704. Moreover, *Joint Stock Soc'y* was decided on summary judgment, not a 12(b)(6) motion to dismiss. In the present case, Apotex has alleged that it filed a substantially complete ANDA and has taken all actions necessary to obtain FDA approval. (Countercl. ¶ 112.)

Bristol-Myers Squibb Co. v. Ben Venue Labs., 90 F. Supp. 2d 540, 545 (D.N.J. 2000) (refusing to find that counterclaimant lacked antitrust standing because it had not received tentative or conditional FDA approval); *see also Biovail*, 49 F. Supp. 2d at 772-73 (refusing to dismiss antitrust claims despite lack of FDA approval); *Glaxo Group Ltd. v. Apotex, Inc.*, 130 F. Supp. 2d 1006, 1008 (N.D. Ill. 2001) (filing of ANDA was sufficient to allege that the defendant was ready or had at least made meaningful preparations to be ready to market the allegedly infringing drug); *Glaxo, Inc. v. Novapharm, Ltd.*, 110 F.3d 1562, 1571 (Fed. Cir. 1997) (allegation that alleged infringer had submitted ANDA sufficient to make FDA approval imminent was sufficient to establish immediacy and reality for declaratory judgment of anticipated infringement). Thus, the fact that Apotex has not alleged that it has received tentative FDA approval is not fatal to its claims.

b. The Outcome Of Merck's Lawsuit Is Not Speculative

Merck also contends that the claimed injury-in-fact is too speculative to support Article III standing because it is dependent on FDA approval, "acceptance" of its proposed generic product and obtaining a decision in this Court (and any appeals) that all nine of Merck's patents are invalid or not infringed. These arguments are without merit.

As mentioned above, Apotex alleged that FDA approval is likely and that there is no reason for Apotex to believe that it will not obtain FDA approval. (Countercl. ¶ 113.) Furthermore, the fact that Apotex sells 260 generic drugs throughout the world, and that it currently sells alendronate sodium in Canada (Countercl. ¶¶ 109, 111) strongly suggests that Apotex's proposed generic version will be accepted in the U.S. market once

it receives FDA approval. Under Rule 12(b)(6), all reasonable inferences from the allegations set forth in Apotex's counterclaim should be drawn in favor of Apotex.

With respect to the patent claims in this case, Apotex alleged that after Merck filed its complaint, Apotex provided Merck with certain information from its ANDA that showed that Apotex does not use a formulation that is covered by Merck's patents. (Countercl. ¶¶ 57, 58.) Merck subsequently provided Apotex with a covenant not to sue. (Countercl. ¶ 59, 63.) Merck's covenant not to sue admits on its face that two claims of one of Merck's patents have been held invalid, and further that Apotex's products will not contain certain elements claimed in Merck's patents. (Countercl. ¶¶ 64, 65.) The most reasonable inference to draw from the fact of Merck's covenant not to sue is that Apotex's generic version of alendronate sodium does not infringe any valid claim of Merck's patents. On a Rule 12(b)(6) motion, this Court should draw all reasonable inferences in favor of Apotex. Thus, it is reasonable to infer that Apotex will be able to obtain a decision from this Court that the patents are invalid or not infringed.[11]

B. Apotex Has Adequately Pled Facts To Overcome *Noerr-Pennington* Immunity

Merck contends that its patent infringement lawsuit against Apotex is immune from antitrust liability under the *Noerr-Pennington* doctrine and that Apotex fails to sufficiently allege that Merck's suit is a "sham." Merck argues that its attempt to make a

[11] The issue in *Whitmore v. Arkansas*, 495 U.S. 149, 159-160, 110 S. Ct. 1717 (1990), the case cited by Merck, was whether a third party could intervene to prevent the execution of a capital defendant who has decided to forgo further judicial proceedings. The Court held that the petitioner lacked injury-in-fact to establish Article III standing because the petitioner, another death row inmate whose sentence was final, would have had to obtain federal habeas relief, be retried, convicted, and again sentenced to death, then the addition of the capital defendant's crimes to the Arkansas' comparative review data base would have had to have led the Supreme Court of Arkansas to set aside a death sentence for the petitioner notwithstanding the petitioner's heinous crime. *Id.* at 157. Thus, the Court held that in that situation the petitioner's injury was too remote for Article III standing. *Id.* at 159.

reasonable investigation prior to filing its lawsuit was thwarted by Apotex's refusal to provide the information it requested, and therefore its lawsuit was not objectively baseless. Merck's arguments are based on (erroneous) issues of fact that are outside of the pleading and should therefore not be considered in a 12(b)(6) motion. Based on the allegations in Apotex's counterclaim, Merck did not have probable cause to sue Apotex, but only filed suit to keep Apotex out of the market for as long as possible. These allegations are sufficient for the "sham" litigation exception to *Noerr-Pennington* immunity.

1. Apotex's Allegations Were Not Made In Bad Faith

Even if the Court were to consider the facts Merck asserts that are not in Apotex's counterclaim, the evidence Merck relies on shows that Apotex did not fail to make good on its offer to provide confidential information as Merck claims. Further, Apotex has sought to withdraw two paragraphs (paragraphs 39 and 42) from its First Amended Answer that referred to Merck's failure to make any request for information.

Apotex acknowledges that it inadvertently overlooked the correspondence attached as Exhibits B, C and D to Merck's response.[12] Indeed, when Merck first brought this to Apotex's attention on November 1, 2006, Apotex immediately sought to substitute a corrected version of its First Amended Answer, which deleted the two paragraphs containing the inaccurate allegations. *See* Apotex's Motion For Leave To Substitute

[12] Merck cannot rely on the correspondence it attached as Exhibits B, C and D to its response because they raise matters outside the pleadings and, contrary to Merck's contentions, Apotex did not rely on these documents in its counterclaim. *See Pension Benefit Guar. Corp.*, 998 F.2d at 1196.

Corrected Exhibits, filed on November 3, 2006.[13] (D.I. 36) Merck inexplicably objected to Apotex's attempt to correct its proposed First Amended Answer. *See* Merck's Answering Brief In Opposition To Apotex's Motion For Leave To Substitute Corrected Exhibits To Its Pending Motion For Leave To Amend, filed on November 22, 2006. (D.I. 44)

While Merck makes much of Apotex's oversight, the fact that Merck had indeed requested confidential information from Apotex prior to filing its infringement lawsuit does not negate Apotex's claims. Merck lawsuit was nevertheless unreasonable.

First, Apotex did not fail to make good on its offer to provide information, as Merck asserts. Apotex alleged that, as required under the Hatch-Waxman scheme, Apotex offered in its paragraph IV certification to provide Merck with certain confidential information in order for Merck to determine whether Apotex's ANDA did in fact infringe Merck's patents, prior to Merck's filing its infringement suit. (Countercl. ¶ 38.) As permitted by the statute, 21 U.S.C. § 355(j)(5)(C)(i)(III), Apotex imposed terms and restrictions on its offer of confidential access. *See* Merck's Ex. A, at p. 3. In particular, Apotex stated that it would permit confidential access to certain information from its proprietary ANDA to "attorneys from one outside law firm" but not to any Merck employees. *Id.*

Merck did not unconditionally accept Apotex's offer of access to confidential information, however. Instead, Merck proposed different terms, *i.e.*, it wanted "at least two in-house litigation counsel" to be able to view the Confidential Information. *See* Merck's Ex. B. In effect, Merck rejected Apotex's offer and made a counteroffer. Apotex

[13] Apotex hereby incorporates by reference its November 3rd Motion for Leave To Substitute Corrected Exhibits To Its Pending Motion For Leave (D.I. 36) and its Reply in Support Thereof, filed on December 1, 2006 (D.I. 45).

was not required to accept Merck's counteroffer. While Apotex subsequently asked for clarification as to the product involved, since Merck neither identified the product nor the ANDA number in its initial request, *see* Merck's Ex. C, Apotex did not accept Merck's counterproposal and therefore was not obligated to provide the requested confidential information.

Thus, Apotex cannot be blamed for Merck's failure to obtain the confidential information offered by Apotex. Merck could have simply accepted Apotex's original offer and conditions. Certainly, Merck could have made an adequate determination of whether Apotex infringed Merck's patents using outside counsel. Instead, Merck chose to file suit without making a reasonable investigation.

Second, Merck's suggestion that had it obtained the confidential information from Apotex prior to filing suit, it might not have filed suit, is demonstrably false. In its paragraph IV letter, Apotex alleged that it did not infringe seven of Merck's patents, and that two of Merck's patents were invalid. (Countercl. ¶¶ 33-36; Merck's Ex. A.) Merck did not need to review Apotex's confidential information to determine whether the two alleged patents were invalid. Indeed, the offer of confidential information need only be made if the notice relates to noninfringement. *See* 21 U.S.C. § 355(j)(5)(C)(i)(III). Yet, Merck sued Apotex on the patents Apotex alleged were invalid, as well.

Third, Merck's claim that it was constrained by the time limits set by the Hatch-Waxman scheme is also disingenuous. Merck would not have lost the right to challenge Apotex's ANDA if it did not sue within 45 days of receipt of Apotex's paragraph IV letter. *See* 35 U.S.C. § 271(e)(2)(A). It would merely have lost the benefit of the 30-month stay by not filing within 45 days. Moreover, Merck delayed until almost half of

the 45-day period elapsed before it requested any information from Apotex, and it did not provide the complete information identifying the specific ANDA or the associated product until almost a week later.[14] Merck obviously was well familiar with the time limits set forth in Hatch-Waxman, specifically that it had 45 days from receipt of Apotex's paragraph IV letter to file an infringement suit in order to obtain the 30-month stay of Apotex's ANDA. If Merck was genuinely interested in making a reasonable investigation of Apotex's contentions in its paragraph IV letter, it should have acted immediately upon receipt of the letter and accepted Apotex's offer of confidential information unconditionally. Instead, Merck unreasonably delayed and then rejected the terms and conditions that Apotex reasonably imposed on its offer of confidential information. Then Merck used the 45-day time limit as an excuse to file suit without making a reasonable investigation. Under these circumstances, Merck's pre-suit inquiry was not reasonable.

The cases relied upon by Merck, principally *Hoffmann-La Roche Inc. v. Invamed Inc.*, 213 F.3d 1359, 1363-65 (Fed. Cir. 2000) and *First Graphics, Inc. v. M.E.P. Cad, Inc.*, 2002 U.S. Dist. LEXIS 14914, at *5-6 (N.D. Ill. Aug. 13, 2002) (Ex. E hereto), are distinguishable. Significantly, neither case is an antitrust action involving the question of whether allegations of sham litigation were sufficient under Rule 12(b)(6).

In *Hoffmann-La Roche*, the defendant moved for Rule 11 sanctions after the plaintiff dismissed its infringement suit once the plaintiff discovered that the defendant's process for making a certain drug did not infringe its process patents. *See Hoffmann-La*

[14] According to Merck's Ex. A, Apotex's paragraph IV letter was received by Merck's patent department on February 28, 2006, while Merck's letter requesting the confidential information was dated March 21, 2006—21 days later. *See* Merck's Ex. B. Merck did not identify the ANDA number or product until its letter dated March 27, 2006. *See* Merck's Ex. D.

Roche, 213 F.3d at 1362. Significantly, *Hoffmann-La Roche* did not involve the statutory scheme under Hatch-Waxman because the patent at issue was a process patent, which does not qualify for listing in the Orange Book. Moreover, the plaintiff in *Hoffmann-La Roche* asked the defendant to disclose the process it was using but because of confidentiality concerns, the defendant declined to disclose its process, and the process could not be determined by reverse engineering a sample of the drug which the defendant had provided. *Id.* at 1361-62.

In the present case, Apotex told Merck in its paragraph IV letter why it did not infringe certain of Merck's patents and why other patents were invalid. (Countercl. ¶ 32-36.) Apotex also alleged that that information was sufficient for Merck to know that Apotex was not infringing any valid patents owned by Merck. (Countercl. ¶ 40, 41, 46-48.) The confidential information in Apotex's ANDA merely confirmed what Apotex had already told Merck in its paragraph IV letter. Moreover, whereas, inquires under Rule 11 are fact specific, *see Hoffman-La Roche*, 213 F.3d at 1365, under Rule 12(b)(6), the Court is required to accept Apotex's allegations as true and to draw all reasonable inferences in its favor.

In *First Graphics*, the defendant patent infringer was seeking attorney's fees under 35 U.S.C. § 285, which allows attorney's fees in exceptional cases under the standard of clear and convincing evidence. *See First Graphics, Inc.*, 2002 U.S. Dist. LEXIS 14914, at *4. Under this heightened standard, the district court in *First Graphics* did not find sufficient evidence that the plaintiff knew its lawsuit was meritless because the plaintiff had in fact performed a pre-filing investigation of the case: it had obtained and reviewed a demo-copy of the software at issue and informational materials about the

program, and it procured two opinion letters construing the patent claims and comparing those claims to the alleged infringing device. *Id.* at *5-6. The plaintiff did not refuse an offer of a fully-functioning copy of the software, as Merck refused Apotex's offer of confidential information in the present case. Moreover, while the plaintiff made its investigation based on other materials besides a fully-functioning copy of the software, Merck made no investigation and had no information other than Apotex's paragraph IV letter which denied infringing any valid claims of Merck's patents and gave specific reasons for its denial.

In any event, Merck has simply raised factual issues which are not appropriate in considering a Rule 12(b)(6) motion to dismiss. Based on the allegations in the counterclaims, Merck has not shown that there are no set of facts that would entitle Apotex to relief.

2. Apotex Sufficiently Alleged That Merck's Suit Was Objectively Baseless

The first part of the Supreme Court's two-part test for the sham litigation exception to *Noerr-Pennington* immunity requires that Merck's underlying lawsuit is "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits." *See Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60-61, 113 S. Ct. 1920 (1993). Merck claims that Apotex's allegations are not sufficient to establish lack of probable cause to file suit because Merck was not required to take Apotex's word for the fact that Apotex did not infringe Merck's patents or Merck's patents were invalid.

First, Apotex did more than just tell Merck that its generic version of alendronate sodium would not infringe any valid claims of Merck's patents, Apotex also made a

certification to the FDA that Merck's patents were invalid or not infringed, and it gave specific reasons for its position on infringement and validity, as the statute requires. (Countercl. ¶¶ 31-36.) In response, Merck refused Apotex's offer of confidential information under the terms and conditions proposed by Apotex, and went ahead and filed suit based only on the information in Apotex's paragraph IV letter, which explicitly denied infringing any valid patents owned by Merck.

Second, Merck's reliance on *First Graphics*, 2002 U.S. Dist. LEXIS 14914, at *8 for its position that a party is not required to accept an opponent's assertion that its case lacks merit is misplaced. The statement in *First Graphics* was made in the context of the defendant's argument that the plaintiff acted in bad faith in refusing to accept its settlement offer. *Id.* at *8. The district court found in that case that the plaintiff's rejection of the settlement offer did not evince bad faith. The details of the settlement offer and the circumstances under which it was made are not discussed in the case. The district court had already found, however, that the plaintiff did an adequate pre-filing investigation because it had at least obtained some information about the defendant's product, including a demo-copy of the allegedly infringing software.

In contrast, Merck had no information concerning Apotex's product other than Apotex's paragraph IV letter prior to filing suit. Thus, Merck had no reason to question Apotex's assertions that its generic version did not infringe and it rejected Apotex's offer of confidential information from which it would have been able to determine whether Apotex's proposed generic would infringe its patents. Under those circumstances, Merck lacked probable cause to sue.

Apotex alleged that in its paragraph IV letter to Merck it told Merck that the products that were the subject of its ANDA would not infringe certain of Merck's patents because its products would not contain certain ingredients claimed in Merck's patents. (Countercl. ¶¶ 34-36.) Additionally, Apotex alleged that Merck knew it was within the ability of one of ordinary skill in the art of drug manufacturing to make generic alendronate sodium tablets without using the ingredients claimed by Merck. (Countercl. ¶¶ 40-41.) "To establish infringement, every element and limitation of the claim must be present in the accused device, literally or by an equivalent." *Inpro II Licensing, S.A.R.L. v. T-Mobile USA, Inc.*, 450 F.3d 1350, 1357-58 (Fed. Cir. 2006) (citing *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 40, 117 S. Ct. 1040 (1997)). Thus, Merck lacked probable cause to sue for infringement based on a theory of literal infringement, and there is nothing alleged that would suggest that Merck had probable cause to sue for infringement under the doctrine of equivalence.

Apotex also alleged that it told Merck in its paragraph IV letter that two of Merck's patents were invalid based upon a prior court decision which held that two claims of one of Merck's patents were invalid. (Countercl. ¶ 33.) Apotex further alleged that prior to filing suit, Merck knew that its claims relating to the once-weekly dosage of alendronate sodium had been held invalid in a final, nonappealable decision, and that the claims in the '329 patent that were related to alendronate sodium were invalid and unenforceable. (Countercl. ¶ 47.) Finally, Apotex alleged that Merck knew prior to filing its infringement suit against Apotex that Merck had no objectively reasonable basis for believing that Apotex was infringing any valid claims of the patents that were the subject of Apotex's paragraph IV certification. (Countercl. ¶ 48.) Based upon these allegations,

which must be assumed true for Merck's 12(b)(6) motion, Merck had no objectively reasonable basis for filing its infringement suit against Apotex.[15]

Apotex need not allege that it showed information to Merck establishing the composition of the tablets it described in its ANDA before Merck filed suit, as Merck contends. Instead, Apotex alleged that it offered to provide Merck with certain confidential information in its ANDA in order for Merck to determine whether Apotex's ANDA did in fact infringe Merck's patents prior to Merck's filing suit. (Countercl. ¶ 38.) The Corrected First Amended Answer, in which paragraphs ¶¶ 39 and 42 are deleted, is silent as to Merck's response. The documents attached to Merck's response demonstrate, however, that Apotex's offer of confidential information was made under certain terms and conditions, as were allowed to be set by statute, and that Merck proposed different terms and conditions when it requested Apotex's confidential information, thus rejecting Apotex's offer and proposing a counteroffer. *See* Merck's Exs. A and B.

The probable cause determination must be based on the facts alleged by Apotex, and not on disputed facts asserted by Merck based on matters raised outside the pleadings. *See In re Wellbutrin SR Antitrust Litig.*, 2006 WL 616292, at *6-7 (E.D. Pa. Mar, 9, 2006) ("The Court's probable cause analysis must therefore be based exclusively on the allegations in Plaintiff's Complaints, regardless of whether those allegations are consistent with the factual findings of other courts.") (Ex. F hereto); *Jarrow Formulas,*

[15] In the event the Court finds that Apotex's allegations regarding Merck's probable cause to sue are not sufficient, Apotex's motion should be denied without prejudice so that Apotex may seek leave to amend its antitrust counterclaim. At the behest of this Court, Merck recently served its interrogatory responses identifying the specific claims in its patents it alleges are infringed by Apotex's ANDA. These interrogatory responses demonstrate that Merck had no objectively reasonable basis to allege infringement either literally, or under the doctrine of equivalence, and no objectively reasonable basis to assert the patents Apotex asserts are invalid.

Inc. v. Int'l Nutrition Co., 175 F. Supp. 2d 296, 310-11 (D. Conn. 2001) ("Here, all that is required is that the complaint allege facts, which, if proven, show that the defendant is not entitled to *Noerr-Pennington* immunity under the sham litigation exception."); *Skinder-Strauss Assocs. v. Mass. Continuing Legal Educ., Inc.*, 870 F. Supp. 8, 10 (D. Mass. 1994) ("Because [the defendant's] counterclaims allege that the lawsuit filed by [the plaintiff] is objectively baseless and conceals an attempt to interfere directly with the business relationships of a competitor, the counterclaims adequately state a claim and should not be dismissed under Fed. R. Civ. P. 12(b)(6)."); *Brotech Corp. v. White Eagle Int'l Techs. Group, Inc.*, 2003 WL 22797730, at *4 (E.D. Pa. Nov. 18, 2003) (allegations that plaintiff's claims were objectively baseless, plaintiff's motivation in filing suit was to pressure defendant into ceding control of its intellectual property in a coerced settlement, and lawsuit was a "sham," were sufficient to allege "sham" litigation) (Ex. G hereto).

Merck's reliance on *Hoffmann-La Roche* and *First Graphics* is misplaced since neither case involves the allegations that are sufficient to establish the sham litigation exception for *Noerr-Pennington* immunity for purposes of Rule 12(b)(6).

Under the second part of the test for sham litigation, which examines the litigant's subjective motivation, "the court should focus on whether the baseless lawsuit conceals an attempt to interfere *directly* with the business relationships of a competitor, through the use of the governmental *process*—as opposed to the *outcome* of that process—as an anticompetitive weapon." *PRE*, 508 U.S. at 60-61 (emphasis in original).

Regarding Merck's subjective intent, Apotex alleged that Merck's practice of filing sham lawsuits against secondary generic filers, including Apotex, presenting covenants not to sue and seeking to dismiss the cases in order to avoid an adverse

judgment on the merits that would terminate the 30-month stay and create a "court decision" triggering event of the first generic applicant's 180-day exclusivity period, is intended to eliminate Apotex and other secondary generic filers from the market for at least the first 180-days after the first generic enters the market. (Countercl. ¶¶ 98, 99, 128, 130.) Thus, Apotex has sufficiently alleged that Merck is using the governmental process in an attempt to interfere with competition in the market for generic alendronate sodium, including competition from Apotex.

In *In re Buspirone Patent Litig.*, 185 F. Supp. 2d 363, 375 n. 5 (S.D.N.Y. 2002), the court held that plaintiffs' allegation "that [the brand manufacturer's] purpose in listing the [patent at issue] in the Orange Book and then bringing the subsequent patent infringement actions...simply to delay the FDA's approval of [the generic manufacturer's] ANDAs for up to thirty months, irrespective of the outcome of the litigations, and knowing that [the brand manufacturer's] claims lacked merit...are sufficient to state the second element [*i.e.*, the subjective element] required for an exception to *Noerr-Pennington* immunity under the *PRE*-standard for purposes of this motion to dismiss." Apotex's allegations regarding Merck's subjective intent are similar to those in *In re Buspirone*.

III. APOTEX'S PROPOSED AFFIRMATIVE DEFENSE IS NOT MOOT

Relying on the arguments it made previously in connection with its motion to dismiss for lack of subject jurisdiction, Merck contends that Apotex's proposed affirmative defenses are moot in light of the covenant not to sue that Merck presented to Apotex. Apotex denies that this case is moot and will rely on the arguments made previously in connection with Merck's motion to dismiss, as Merck has done.

CONCLUSION

For the foregoing reasons, Apotex respectfully requests that the Court grant leave for Apotex to file its First Amended Answer, Affirmative Defenses and Counterclaims.

POTTER ANDERSON & CORROON LLP

OF COUNSEL:

A. Sidney Katz
Robert B. Breisblatt
Louise T. Walsh
Michael Krol
Welsh & Katz, Ltd.
120 S. Riverside Plaza, 22nd Floor
Chicago, Illinois 60606
Tel: (312) 655-1500
Fax: (312) 655-1501

By: */s/ Richard L. Horwitz*

Richard L. Horwitz (#2246)
Kenneth L. Dorsney (#3726)
Hercules Plaza, 6th Floor
1313 N. Market Street
P. O. Box 951
Wilmington, DE 19899
Tel: (302) 984-6000
rhorwitz@potteranderson.com
kdorsney@potteranderson.com

Dated: December 8, 2006

Attorneys for Defendant Apotex, Inc.

766410 / 30234

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I, Richard L. Horwitz, hereby certify that on December 8, 2006, the attached document was hand delivered on the following person and was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

Mary B. Graham
James W. Parrett, Jr.
Morris, Nichols, Arsht & Tunnell, LLP
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899-1347

I hereby certify that on December 8, 2006, I have Electronically Mailed the attached document to the following:

John F. Lynch
Howrey, LLP
750 Bering Drive
Houston, TX 77057-2198
lynchj@howrey.com

Nicolas G. Barzoukas
Suzy S. Harbison
Jason C. Abair
Weil, Gotshal & Manges
700 Louisiana, Suite 1600
Houston, TX 77002
nicolas.barzoukas@weil.com
suzy.harbison@weil.com
jason.abair@weil.com

I hereby certify that on December 8, 2006, I have Federal Expressed the attached document to the following non-registered participants:

Paul D. Matukaitis
Merck & Co., Inc.
One Merck Drive
Whitehouse Station, NJ 08889-0100

Edward W. Murray
Gerard M. Devlin
Merck & Co., Inc.
126 E. Lincoln Avenue RY28-320
Rahway, NJ 07065-0907

/s/ Richard L. Horwitz

Richard L. Horwitz
Kenneth L. Dorsney
Potter Anderson & Corroon LLP
Hercules Plaza – Sixth Floor
1313 North Market Street
P.O. Box 951
Wilmington, DE 19899-0951
(302) 984-6000
rhorwitz@potteranderson.com
dmoore@potteranderson.com

728942

EXHIBIT A

April 11, 2006

Dear Pravastatin ANDA applicant:

This letter is prompted by the March 16, 2006, opinion of the District of Columbia Circuit Court of Appeals, *Teva Pharmaceuticals USA, Inc. v. FDA*, Nos. 05-5401 & 05-5460, 2006 U.S. App. LEXIS 6384 (D.C. Cir. Mar. 16, 2006) ("*Teva III*"). We are amending our response to the letter submitted by Apotex Inc. on September 7, 2004. Apotex sought a determination that a dismissal of a declaratory judgment action brought by Apotex against Bristol-Myers Squibb Company ("Bristol"), *Apotex Inc. v. Bristol-Myers Squibb Co.*, No. 04-2922 (Jul. 23, 2004 stipulation and order), constituted a "court decision trigger" beginning the 180-day period of marketing exclusivity for the first abbreviated new drug application ("ANDA") applicant to make a "paragraph IV" certification challenging a patent for Pravastatin Sodium Tablets 10 mg., 20 mg., 40 mg., and 80 mg. ("pravastatin"). FDA previously determined in a letter dated June 28, 2005, that the dismissal constituted a court decision trigger, based on an interpretation of the court decision trigger provision, Section 505(j)(5)(B)(iv)(II) of the Federal Food, Drug, and Cosmetic Act ("FDCA" or the "Act") (21 U.S.C. § 355(j)(5)(B)(iv)(II)), that the agency believed itself compelled to apply as a result of two decisions of the D.C. Circuit: *Teva Pharm., USA, Inc. v. FDA*, 182 F.3d 1003 (D.C. Cir. 1999) ("*Teva I*") and *Teva Pharm., USA, Inc. v. FDA*, No. 99-5287, 2000 U.S. App. LEXIS 38,667 (D.C. Cir. Nov. 15, 2000) ("*Teva II*"). Specifically, FDA believed that *Teva I* and *II* required the agency to treat a dismissal of a declaratory judgment action for lack of jurisdiction as a court decision trigger if the patentee is estopped from enforcing its patent against the declaratory plaintiff.

Teva Pharmaceuticals USA, Inc. challenged FDA's June 28, 2005 decision in district court. *Teva Pharms. USA, Inc. v. FDA*, 398 F. Supp. 2d 176 (D.D.C. 2005). On appeal, the *Teva III* court vacated the judgment of the district court with instructions to vacate the FDA's decision and remand to the agency for further proceedings. The court held that FDA's decision was arbitrary and capricious because "[t]he FDA mistakenly thought itself bound by our decisions in *Teva I* and *Teva II*." *Teva III*, 2006 U.S. App. LEXIS 6384, at *12. In the court's view, the *Teva I* and *Teva II* decisions had been decided purely on procedural grounds and "left the final decision" of statutory interpretation to FDA. *Id.* at *9.

FDA has therefore undertaken to interpret the statute in light of the *Teva III* court's direction "'to bring its experience and expertise to bear in light of competing interests at stake' and make a reasonable policy choice." *Id.* at *13 (quoting *PDK Labs., Inc. v. DEA*, 362 F.3d 786, 797-98 (D.C. Cir. 2004)). As explained in greater detail below, FDA interprets the language of the court decision trigger provision, "the date of a decision of a court . . . holding the patent which is the subject of the certification to be invalid or not infringed," to require a court decision with an actual "holding" on the

merits that the patent is invalid, not infringed, or unenforceable. The holding must be evidenced by language on the face of the court's decision showing that the determination of invalidity, noninfringement, or unenforceability has been made by the court. FDA's experience in making court decision trigger determinations bears out the difficulty in implementing a broader, estoppel-based standard that requires the agency to evaluate whether the patentee is estopped from suing for infringement. FDA's "holding-on-the-merits" interpretation adheres closely to the language of the statute, and will provide a bright line that is more easily administrable by FDA and that will enable industry to make appropriate business planning decisions.

Applying FDA's interpretation to the facts of this case, FDA has determined that the July 23, 2004, Apotex-Bristol dismissal does not constitute a court decision trigger of 180-day exclusivity for pravastatin because there is no language on the face of the dismissal evidencing that the court held on the merits that any of the subject patents were invalid, not infringed, or unenforceable.

I. Statutory and Procedural Background

A. 180-Day Exclusivity and the Court Decision Trigger

Under section 505(j)(2)(A)(vii), ANDA applicants must make one of four certifications (commonly referred to by the four sub-paragraphs of section 505(j)(2)(A)(vii) establishing them) to certain patents, claiming the drug or a use of the drug for which the ANDA applicant is seeking approval. The certifications are: a "paragraph I" certification that patent information has not been filed; a "paragraph II" certification that the patent has expired; a "paragraph III" certification of the date the patent will expire; or a "paragraph IV" certification that the patent is invalid, not infringed, or not enforceable. 21 C.F.R. § 314.94(a)(12)(i)(A).

A paragraph I or II certification indicates that the applicant believes that the patent does not bar immediate approval of the ANDA. A paragraph III certification indicates that the applicant is not challenging the validity or applicability of the patent and that the applicant is seeking ANDA approval only after the patent expires. A paragraph IV certification indicates that the ANDA applicant disputes the applicability or validity of that patent.

An ANDA applicant making a paragraph IV certification must provide notice to the new drug application (NDA) holder and patent owner stating that the ANDA has been filed and describing why the patent is invalid, will not be infringed, or is unenforceable. 21 U.S.C. § 355(j)(2)(B); 21 C.F.R. § 314.94(a)(12)(i)(A). This notice provides the NDA holder and patent owner the opportunity to bring suit for patent infringement prior to FDA's granting marketing approval for the ANDA applicant's product. In certain cases, if the NDA holder or patent owner sues the ANDA applicant for patent infringement within 45 day of receipt of the notice, FDA must stay approval of the ANDA for 30 months (21 U.S.C. § 355(j)(5)(B)(iii)). The FDCA provides that an ANDA applicant cannot bring an action for declaratory judgment unless this 45-day period has expired,

neither the NDA holder nor the patent owner has sued the ANDA applicant for patent infringement before the expiration of that period, and, as applicable, the ANDA applicant has offered these parties confidential access to its application for the purpose of determining whether to bring a patent infringement suit. 21 U.S.C. § 355(j)(5)(C)(i) (2005).

Section 505(j)(5)(B)(iv) of the Act governs FDA's 180-day exclusivity determinations. The statute provides 180 days of marketing exclusivity as an additional incentive and reward to the first ANDA applicant to expose itself to the risk of being sued for infringing a patent that is the subject of the paragraph IV certification. It does so by delaying approval of subsequent ANDAs containing later paragraph IV challenges to the patent until the expiration of 180 days after a triggering event. The applicable version of the statute reads as follows:

> If the application contains a certification described in subclause IV of paragraph (j)(2)(A)(vii) and is for a drug for which a previous application has been submitted under this subsection [containing][1] such a certification, the application shall be made effective not earlier than one hundred and eighty days after -
>
> (I) the date the Secretary receives notice from the applicant under the previous application of first commercial marketing of the drug under the previous application, or
>
> (II) the date of a decision of a court in an action described in clause (ii) holding the patent which is the subject of the certification to be invalid or not infringed,
>
> whichever is earlier.

21 U.S.C. § 355(j)(5)(B)(iv) (2002).[2] Under this provision, either of two events can trigger the start of the exclusivity period: (1) the commercial marketing of the drug product as set forth in subparagraph (I); or (2) an applicable court decision as set forth in

---

[1] Courts reviewing the statute have commented that the word "continuing" reflects a typographical error and should be "containing." *See, e.g., Purepac Pharm. Co. v. Friedman*, 162 F.3d 1201, 1203 n.3 (D.C. Cir. 1998); *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1064 n.3 (D.C. Cir. 1998).

[2] Congress amended 21 U.S.C. § 355(j) in late 2003. *See* The Access to Affordable Pharmaceuticals provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (Dec. 8, 2003) ("MMA"). The majority of the amendments pertaining to 180-day exclusivity do not apply to the exclusivity determinations for the pravastatin ANDAs because the earliest ANDA containing a paragraph IV certification was submitted before the December 8, 2003, enactment date of the MMA. *See id.* § 1102(b)(1). The MMA does, however, apply to the court decision trigger determination at issue insofar as it defines a "decision of a court" as a final judgment from which no appeal can be or has been taken. *See* MMA § 1102(b)(3) (defining "decision of a court" for drugs for which a paragraph IV certification was filed before enactment of the MMA and for which there has been no triggering court decision as of the date of enactment, December 8, 2003).

subparagraph (II). Subparagraph (II) is commonly referred to as the "court decision trigger."

By regulation, FDA has long interpreted the court decision trigger to be satisfied not only by a decision of a court holding the patent invalid or not infringed, but also by a decision holding the patent unenforceable. 21 C.F.R. § 314.107(c)(1)(ii). In the preamble to the 1994 final rule implementing the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Amendments" to the FDCA), the agency explained that references in section 505 to patent invalidity and noninfringement should be interpreted to embrace unenforceability so as to be consistent with "Congress' obvious intent in allowing patent challenges under section 505," and to avoid absurd results. 59 Fed. Reg. at 50,339 (citing *Merck v. Danbury Pharmacal, Inc.*, 694 F. Supp. 1 (D. Del. 1988), *aff'd*, 873 F.2d 1418 (Fed. Cir. 1989)).

B. The *Teva* Cases

In the *Teva* cases, FDA was asked to determine whether the dismissal of a declaratory judgment action for lack of subject matter jurisdiction in a patent case between Teva and Syntex constituted a court decision trigger of exclusivity for Apotex (then Torpharm) for the drug ticlopidine. *Teva I*, 182 F.3d at 1006-07. FDA determined that the Teva-Syntex dismissal was not a "decision of a court" or a "holding," as required by the statute. *Id.* On appeal, the D.C. Circuit concluded that FDA's determination that there had been no court decision trigger was arbitrary and capricious. *Id.* at 1007-10. The court remanded to the agency for an explanation of, *inter alia*, why FDA did not recognize that a dismissal based on representations that estopped the patentee from suing for infringement constituted a court decision trigger. *Id.*

On remand, FDA attempted to explain its decision, but the district court, Judge Kollar-Kotelly, rejected the agency's explanation. *Teva Pharms. USA, Inc. v. FDA*, No. 99-67, 1999 U.S. Dist. LEXIS 14,575 at *22-23 (Aug. 19, 1999) ("The FDA is bound by the Court of Appeals' determination that the purpose of the court decision trigger is to ensure that the patent-holder is estopped from suing the ANDA applicant."). The D.C. Circuit affirmed the district court's decision in an unpublished decision stating that "for the reasons cited . . . in *Teva I* and by the District Court, the judgment of the agency fails for want of reasoned decision-making." *Teva II*, 2000 U.S. App. LEXIS 38,667, at *6. Following the *Teva II* decision, FDA has believed that it was bound to apply an estoppel-based standard when making court decision trigger determinations, and initially applied this standard with respect to the pravastatin products at issue here.

C. FDA's June 28, 2005 Decision

Bristol is the holder of an approved NDA 19-898 for pravastatin sodium tablets, which it markets under the brand-name Pravachol. Pravachol is approved for the primary and secondary prevention of coronary events and for treating hyperlipidemia. Bristol listed four relevant patents in the Orange Book with respect to its drug: U.S. Patent Nos. 4,346,227 ("the '227 patent"); 5,030,447 ("the '447 patent"); 5,180,589 ("the '589 patent"); and 5,622,985 ("the '985 patent"). Several ANDA applicants, including Apotex and Teva, have submitted ANDAs containing paragraph IV certifications to the '447, '589, and '985 patents. The '227 patent and its pediatric exclusivity expires on April 20, 2006.[3] Any applicant that has submitted a paragraph III certification to the '227 patent is thus precluded from marketing the drug at least until that date.

Apotex notified Bristol of its paragraph IV certifications to the '447, '589, and '985 patents, but Bristol declined to sue Apotex for infringement. Apotex then sued Bristol in the United States District Court for the Southern District of New York (*Apotex Inc. v. Bristol-Myers Squibb Co.* (No. 04 CV 2922)) for declaratory judgment of non-infringement and/or invalidity of those patents. The case was dismissed by a stipulation and order issued on July 23, 2004.

The order recited that Bristol had "repeatedly represented and assured Apotex that, notwithstanding any disagreement on the scope or interpretation of the claims of the '447, '985, and '589 patents, it had no intention to bring suit against Apotex for infringement." Apotex stipulated to dismissal of the case for lack of subject matter jurisdiction based on those "pre-Complaint representations." Both parties signed the stipulation and order, which the court endorsed as "so ordered."

By letter dated September 7, 2004, Apotex requested a determination from FDA that the July 23, 2004 stipulated order dismissing Apotex's declaratory judgment action constituted a "decision of a court" under section 505(j)(5)(B)(iv)(II) that triggered any 180-day exclusivity for pravastatin. In view of the *Teva* cases, FDA believed itself obliged to apply an estoppel-based standard in determining whether the July 23, 2004 order qualified as a court decision trigger. In its June 28, 2005 decision, the agency determined that Bristol's assurances to Apotex that it would not sue for infringement estopped Bristol from suing Apotex for infringement. Thus, under the estoppel-based standard FDA believed *Teva I* mandated, FDA found that the dismissal qualified as a court decision under section 505(j)(5)(B)(iv)(II), triggering the running of 180-day exclusivity for the '447, '589, and '985 patents.

[3] Pediatric exclusivity is intended as an incentive to sponsors to conduct and submit to FDA studies requested by the agency on the use of drugs in pediatric populations. It is a six-month exclusivity that attaches to any listed patent or exclusivity for the drug studied. 21 U.S.C. § 355a.

D. *Teva III*

On July 26, 2005, Teva sued FDA, arguing that FDA's June 28, 2005 decision was based on the agency's erroneous belief that *Teva I* and *Teva II* required the agency to apply an estoppel-based standard. Alternatively, Teva argued that even if the *Teva* decisions did impose an estoppel-based standard for the court decision trigger, Bristol's assurances to Apotex were insufficient to effect a complete estoppel. Teva additionally argued that the dismissal had been made effective not by the court but by the parties under Federal Rule of Civil Procedure 41(a)(1)(ii), and as such lacked sufficient judicial involvement to constitute a "decision" or a "holding" of the court.

The district court agreed with Teva that the dismissal had been made effective under Rule 41(a)(1)(ii) and lacked sufficient "judicial imprimatur" to constitute a court decision trigger of 180-day exclusivity. *Teva Pharms. USA, Inc. v. FDA*, 398 F. Supp. 2d 176, 190 (D.D.C. 2005) (Bates, J.). The court stated, however, that Bristol's statements to Apotex were sufficient to preclude Bristol from suing for infringement, concluding that "[t]his case thus embodies the peculiar circumstance in which the words of [Bristol] are preclusive, but they are not part of a 'decision' or 'holding' within the meaning of the Hatch-Waxman Act." *Id.* at 192 n.6. The district court did not reach the question of whether *Teva I* and *Teva II* had established a substantive rule binding upon FDA.

On appeal, the D.C. Circuit determined that "[t]he FDA mistakenly thought itself bound by our decision in *Teva I* and *Teva II*," and held that "[t]his error renders [the agency's] decision arbitrary and capricious." *Teva III*, 2006 U.S. App. LEXIS 6384, at *12. The court explained that it had never established a requirement to apply the estoppel standard as an interpretation of the court decision trigger. *Id.* at *8-10. Rather, *Teva III* held that *Teva I* had simply found FDA's reasoning inadequate for the reasons discussed in that decision. *Id.* at *9; *see also* section II.A., *infra*. Concluding that "FDA still has not answered the questions put to it by the *Teva I* court," *id.* at *13 n.5, the court vacated the district court's judgment and directed the district court to remand to the agency to interpret the court decision trigger provision in view of the agency's own expertise and appropriate policy considerations. *Id.* at *13.

II. FDA's Interpretation of the Court Decision Trigger Provision

In accordance with the *Teva III* court's determination that FDA is not bound to apply the estoppel-based standard discussed in *Teva I*, FDA has brought its experience to bear and now makes an independent interpretation of the statute. FDA has determined that it is most appropriate to interpret the statute consistently with its plain language. Thus, the agency is interpreting the court decision trigger provision to require a *decision* of a *court* that on its face evidences a *holding* on the merits that a patent is invalid, not infringed, or unenforceable. This interpretation follows most readily from the statutory language and FDA's long-standing regulation including unenforceability as a separate basis for a court decision trigger. 21 U.S.C. § 355(j)(5)(B)(iv)(II) ("the date of a *decision* of a *court* . . . *holding* the patent which is the subject of the certification to be invalid or not infringed") (emphasis added); *see also* 21 C.F.R. § 314.107(c)(1)(ii) ("The date of a

decision of the *court holding the relevant patent invalid, unenforceable, or not infringed.*") (emphases added).[4]

A "holding" is generally defined to mean "[a] court's determination of a matter of law pivotal to its decision; a principle drawn from such a decision." Black's Law Dictionary at 737 (7th ed. 1999). The statute's express requirement of a "holding" that the patent is "invalid" or "not infringed" indicates that the court must resolve the issues of invalidity, noninfringement, and unenforceability (pursuant to FDA's regulation) on the merits. *See id.* at 1003 (defining "merits" as referring to "[t]he elements or grounds of a claim or defense; the substantive considerations to be taken into account in deciding a case, as opposed to extraneous or technical points, esp. of procedure"). Under the agency's interpretation, in the court decision trigger context, the holding must be evidenced by a statement on the face of the court's decision demonstrating that the court has made a determination on the merits of patent invalidity, noninfringement, or unenforceability.

A. FDA's Response to *Teva I*

In reaching this interpretation, FDA is mindful of the *Teva I* court's criticism of the agency's original position, as well as the *Teva III* court's view that FDA has never adequately addressed that criticism. FDA addresses the specific issues raised in *Teva I* below.

1. FDA's Interpretation is Consistent with the Purpose of the Statute and Will Promote Industry Certainty and Administrative Workability

FDA acknowledges the *Teva I* court's discussion of broader definitions of "decision" and "holding" as potentially including dismissals with preclusive effect. *Teva I*, 182 F.3d at 1008. However, the *Teva III* court has determined that *Teva I's* discussion is not binding upon the agency. *Teva III*, 2006 U.S. App. LEXIS 6384, at *12.

Teva I further suggested that estoppel was a relevant consideration for the court decision trigger because a different view would allow the patent holder to manipulate the system and delay generic competition by stating that it would not enforce its patent. *Teva I*, 182 F.3d at 1009. That result, in the court's view, would be contrary to the purpose of the statute. *Id.* FDA does not believe, however, that a narrower, textually-based approach is contrary to the purpose of the statute. The court decision trigger provision

[4] The D.C. Circuit has found that the court decision trigger provision is ambiguous. *See Teva I*, 182 F.3d at 1007-08 (noting that the terms "holding" and "decision" are subject to interpretation); *see also Teva III*, 2006 U.S. App. LEXIS 6384 at *12 (assuming, in accordance with *Teva I*, that the statute is ambiguous). To the extent that there is ambiguity in any of the terms, such as "decision," "holding," "invalid," "not infringed," and [by regulation] "unenforceable," FDA's interpretation is permissible and hews more closely to the language of the statute than the estoppel-based approach that the agency believed was compelled by *Teva I* and *Teva II*.

expressly requires a decision of a court holding in favor of the ANDA applicant. The agency's "holding-on-the-merits" standard may provide a more limited trigger than an estoppel-based standard, but it is Congress itself that chose to impose the requirements of a "decision of a court" and a "holding." The estoppel-based standard, by contrast, has the anomalous result of substituting the agency's subsequent determination of preclusive effect for a court's holding on the merits.

Elsewhere, the D.C. Circuit has recognized that the exclusivity provision reflects a Congressional balancing of competing policy goals. *See Teva Pharmaceutical Indus. v. FDA*, 410 F.3d 51, 54 (D.C. Cir. 2005). "Because the balance struck . . . is quintessentially a matter for legislative judgment," the interpretation should "attend closely to the terms in which Congress expressed that judgment." *Id.* FDA believes that it is appropriate to apply the most facially supportable interpretation of the statutory language to give effect to Congress's purpose for the court decision trigger provision, and that nothing less than a court decision with a holding on the merits of the patent claims should qualify as a court decision trigger. The estoppel-based approach, by contrast, renders the terms "decision," "holding," and "invalid or not infringed" superfluous, in contravention of accepted canons of statutory construction. *See, e.g, Bailey v. United States*, 516 U.S. 137, 146 (1995) (superseded by statute on other grounds) ("We assume that Congress used [the] terms because it intended each term to have a particular, nonsuperfluous meaning."). Indeed, pre-*Teva I*, the D.C. Circuit suggested that a proper interpretation of the court decision trigger should give substantive effect to the terms that Congress chose. *See Purepac Pharm. Co. v. Friedman*, 162 F.3d 1201, 1205 n.6 (D.C. Cir. 1998) ("Suppose further that a first applicant is sued but that the suit does not result in a judicial decision finding the patent not infringed or invalid, so that the judicial decision trigger in § 355(j)(5)(B)(iv) is not activated. This could happen if, for instance, the suit is dropped or settled.").

Further, the law on estoppel relevant in the court decision trigger context is not well developed. In fact, the Federal Circuit law to which the D.C. Circuit looked in *Teva I* to determine whether a particular representation has estoppel effect generally addresses whether there is sufficient reasonable apprehension of suit to support a declaratory judgment action, and not, as in the *Teva I* court's inquiry, whether the patentee is ultimately estopped from suing for infringement.[5] In short, applying the estoppel standard articulated by the *Teva I* court would often require FDA to resolve factually intensive questions with little guidance from the courts on how to apply the facts to the law.

Estoppel can be raised in different contexts, and the agency foresees that an estoppel-based approach could require FDA to make determinations based on a host of factors regarding whether a patentee may be equitably estopped from suing a particular ANDA applicant. *See, e.g., A.C. Aukerman Co. v. R.L. Chaides Constr. Co.*, 960 F.2d

[5] *See Teva I*, 182 F.3d at 1008-08 (citing *Super Sack Mfg. Corp. v. Chase Packaging Corp.*, 57 F.3d 1054, 1059 (Fed. Cir. 1995); *Spectronics Corp. v. H.B. Fuller Co.*, 940 F.2d 631, 636-38 (Fed. Cir. 1991); and *Fina Research, S.A. v. Baroid Ltd.*, 141 F.3d 1479, 1483-84 (Fed. Cir. 1998)).

1020, 1028 (Fed. Cir. 1992) (en banc) (noting factors relevant to equitable estoppel: (1) misleading conduct by the patentee indicating that it will not enforce its patent; (2) reliance by the alleged infringer; and (3) material prejudice to the alleged infringer if the patentee is allowed to proceed with its claim). Such determinations are often quite subjective, dependent on an infinite variety of factual contexts, and provide scant basis for predictability to the regulated industry.

In addition, the estoppel-based approach has been difficult to apply and has led to uncertainty. Experience has shown, for example, that declaratory judgment actions may be dismissed for a variety of reasons, not all of which concern representations with preclusive effect that can then serve as a proxy for a finding of estoppel. *See, e.g., Teva Pharms. USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1333 (Fed. Cir.), *cert. denied*, 126 S. Ct. 473 (2005) (dismissing declaratory judgment action for lack of subject matter jurisdiction despite the patentee's refusal to provide assurance that it would not sue). Indeed, *Teva I* and *Teva II*, as well as the instant pravastatin case, demonstrate the difficulty of applying an estoppel-based standard that requires the agency to evaluate the underlying reasons for a dismissal — and the very low likelihood of industry certainty under such a standard.[6]

FDA is ill-equipped to make fact-based determinations concerning whether certain statements or actions of a company in litigation to which FDA is not a party may estop that company from enforcing its patent. FDA's interpretation of the court decision trigger provision as requiring a holding on the merits will enable the agency to rely on the face of the court's decision to determine whether there has been a holding that a patent is invalid, not infringed, or unenforceable. As *Teva I* and *Teva II* demonstrate, an estoppel-based approach inexorably spawns subsequent litigations concerning FDA's estoppel determinations — litigations that can be avoided under a clearer, textually-based standard.

2. FDA's Interpretation is Consistent with its Regulation, which Includes Unenforceability as a Separate Basis for a Court Decision Trigger

The *Teva I* court requested that FDA explain how FDA's decision that the Teva-Syntex dismissal was not a court decision trigger was consistent with FDA's regulation including unenforceability as a basis for the court decision trigger. *Id.* at 1009-10. *Teva I* suggested that FDA's position was "absurd" because FDA's regulation included unenforceability, but FDA refused to acknowledge a dismissal that had the apparent effect of unenforceability as a court decision trigger. *Id.*

---

[6] In the pravastatin case, for example, the district court agreed with FDA that Bristol was estopped from suing Apotex for infringement, but for different reasons. *Compare Teva*, 398 F. Supp. 2d at 192 n.6 (finding preclusion based on Bristol's representations having "prevent[ed] any reasonable apprehension from arising"); *with* FDA's June 28, 2005 letter at 4 (finding preclusion based on Bristol's repeated assurances that it had no intention to sue Apotex for infringement).

FDA's regulation interpreting the court decision trigger states that the trigger occurs on: "[t]he date of a decision of the court holding the relevant patent invalid, unenforceable, or not infringed." 21 C.F.R. § 314.107(c)(1). FDA's inclusion of "unenforceable" in its regulation serves the salutary purpose of encouraging patent challenges based on unenforceability. *See* 59 Fed. Reg. at 50,339. The regulation, consistent with the statute, expressly requires that there be a court "decision" and a "holding" of unenforceability.

FDA does not believe that a patentee's statements concerning its intentions not to enforce a patent, even if reflected in the dismissal, constitute a court's "decision . . . "holding" a patent unenforceable. As explained in section II.A.1., *supra*, FDA rejects an estoppel-based interpretation of the statute based on a patentee's representations. As noted, a declaratory judgment action can be dismissed for a variety of reasons, and such a dismissal cannot uniformly serve as a proxy for a determination of preclusive effect. Even if a patentee's representations have the *apparent* effect of rendering a patent unenforceable vis-à-vis a particular ANDA applicant, in the agency's view, a *holding* of unenforceability must result from a *court's* consideration of that issue on the merits, rather than *FDA's* evaluation of the effect of a patentee's statement. The estoppel-based approach turns the statutory language on its head, by compelling FDA — rather than a court, as the statute seemingly requires — to effectively make a "decision" and a "holding" of unenforceability. Such patent-related decisions are not within the agency's expertise, nor does the statute require FDA to make those decisions. FDA's statutory and regulatory interpretation is not "absurd" because it is narrower than the estoppel-based standard. The agency's interpretation gives full effect to each word of the statute and regulation and will provide greater certainty than the estoppel-based standard.

3. FDA's Interpretation is Consistent with the FDA's 180-day Exclusivity Guidance and the *Granutec* Decision

Teva I also concluded that FDA had not adequately explained its position on the Teva-Syntex dismissal with regard to (a) FDA's "case-by-case" approach to exclusivity set forth in a guidance document, *180-Day Generic Drug Exclusivity under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act* (June 1998) (180-day exclusivity guidance); or (b) why the agency recognized a grant of partial summary judgment of noninfringement based on a patent holder's admission as a court decision trigger in *Granutec, Inc. v. Shalala*, 139 F.3d 889, 1998 WL 153410 (4th Cir. Apr. 3, 1998) (unpublished opinion), but did not consider the Teva-Syntex dismissal for lack of subject matter jurisdiction a court decision trigger even though it too arose from statements made by the innovator. *Id.* at 1010-11.

The regulatory landscape has changed dramatically since FDA's original determination that the Teva-Syntex dismissal did not constitute a court decision trigger. At that time, FDA was undertaking rulemaking and regulating directly from the statute in the interim, using a "case-by-case" approach to make its exclusivity determinations. *See* 180-day exclusivity guidance. *Teva I* suggested that FDA had failed to adopt any particular interpretation of the statute, and also had not "abide[d] by the commitments it

made in the 'Guidance for Industry' as to how it would proceed until a new rulemaking was completed." *Id.*

Just a few days after the *Teva I* decision, in proposing a rule, FDA rejected a suggestion that a dismissal for lack of jurisdiction based on a lack of case or controversy should constitute a court decision trigger. 180-Day Generic Drug Exclusivity in Abbreviated New Drug Applications, 64 Fed. Reg. 42,873, 42,881 (Aug. 6, 1999) (proposed rule). Rather, the agency proposed a 180-day "triggering period," during which there would have to be either a favorable court decision or commercial marketing of the drug. *Id.* at 42,877. If neither of those events occurred, the first ANDA applicant would lose its eligibility for exclusivity. *Id.* Under the "triggering period" approach, subsequent applicants would not be blocked indefinitely from approval, and would thus presumably have no need to seek to trigger exclusivity by bringing declaratory judgment actions and thereby raising the myriad issues that arose in the *Teva* litigations. *Id.* at 42,881.

FDA withdrew that proposed rule in 2002, however, in part due to its belief that the *Teva I* "holding was directly at odds with the approach the agency proposed in the August 1999 proposed rule to deal with dismissals of declaratory judgment actions." 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications, 67 Fed. Reg. 66,593, 66,594 (Nov. 1, 2002) (withdrawal of proposed rule) ("After careful consideration of the comments on the August 1999 proposed rule and multiple court decisions affecting the agency's interpretation of the provisions of the act relating to 180-day exclusivity and ANDA approvals, FDA has concluded that it is appropriate to withdraw the August 1999 proposed rule at this time."). Following FDA's withdrawal of its proposed rule, Congress substantially amended the 180-day exclusivity provision in the MMA. *See* note 2, *supra.* FDA determined not to expend its resources crafting a regulation that would be vulnerable to challenge if it diverged from *Teva I* and would in any event become less relevant in the near future due to Congress's substantial revision of the 180-day exclusivity provision, which ultimately eliminated the court-decision trigger provision (but provided for forfeiture of exclusivity in certain circumstances).[7]

Now, however, FDA is independently interpreting the statute in accordance with the direction of the *Teva III* court. For all of the reasons explained above, FDA's interpretation here is fully consistent with the statutory language and the extensive regulatory and judicial history concerning the agency's treatment of the court decision trigger issue.

---

[7] It bears noting that one event that can trigger forfeiture under the MMA is a "a settlement or consent decree that enters a final judgment that includes a finding that the patent is invalid or not infringed." 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(BB) (2005). As explained above, the MMA amendments do not apply to pravastatin except in one respect (*see* note 2, *supra*) and are not at issue in this decision. The agency's determination to apply the "holding-on-the-merits" standard under the pre-MMA statute does not reflect an agency view as to the proper scope or interpretation of this forfeiture provision or any other forfeiture provision in the MMA.

Teva I also suggested that the Teva-Syntex dismissal should satisfy the court decision trigger requirement because it "support[ed] estoppel to the same extent as the grant of partial summary judgment at issue in *Granutec*." *Teva I*, 182 F.3d at 1011. For the reasons explained in section II.A.1, *supra*, however, FDA does not believe that the court decision trigger provision should be interpreted to embrace dismissals based on underlying statements that have estoppel effect unless the decision evidences a court holding on the merits of the patent claims. Applying the "holding-on-the-merits" interpretation, it is clear that the Teva-Syntex dismissal was materially distinguishable from the decision at issue in *Granutec*.

The underlying decision in *Granutec* was a memorandum decision by the court granting a motion for partial summary judgment of noninfringement based on the patentee's concession that the defendant's product did not infringe. *Glaxo, Inc. v. Boehringer Ingelheim Corp.*, No. 95-CV-01342 (D. Conn. Oct. 7, 1996) (memorandum decision). The court's grant of summary judgment is clearly a holding on the merits of patent noninfringement as a matter of law.[8] *See* Fed. R. Civ. Proc. 56(c) ("The judgment sought shall be rendered forthwith if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law."). In contrast, the Teva-Syntex case was dismissed on jurisdictional grounds based on Teva's lack of a reasonable apprehension of suit. *See Teva I*, 182 F.3d at 1004. Once the court recognized that it lacked jurisdiction, it appropriately refused to decide the merits of the case and granted Syntex's motion to dismiss. Thus, FDA's textually-based interpretation is entirely consistent with its determination that there was a court decision trigger in *Granutec*, but not in the Teva-Syntex case.

B. FDA's Interpretation is Most Facially Supportable and is Consistent with Important Policy Goals of Regulatory Clarity and Certainty

The legislative history for the Hatch-Waxman amendments clearly reflects a congressional intent to expedite approval of generic drugs and promote competition in the drug marketplace. H.R. Rep. No. 98-857, Pt. 1, 98th Cong., 2d Sess. at 14-15, *reprinted in* 1984 U.S.C.C.A.N. 2647-48. However, to achieve these policy goals, Congress established a regime that depends on ANDA applicants to challenge drug patents to enable earlier approval of generic drugs and, thereby, promote competition. Congress clearly believed that ANDA applicants needed an incentive beyond the prospect of earlier generic market entry to take on the litigation risks associated with challenging drug patents. This Congressional belief is manifested in the statutory provision for 180-day exclusivity under section 505(j)(5)(B)(iv).

[8] Consistent with its decision in the *Granutec* case, FDA's interpretation does not demand, and the agency does not intend to limit its scope to, court decisions following a full trial. The statutory language "decision of a court" in section 505(j)(5)(B)(iv)(II) does not require such a narrow reading; nor does the legislative history appear to indicate Congressional intent for the language to be read in such a manner.

A relatively broad interpretation of the court decision trigger, such as the estoppel standard, makes it easier to trigger 180-day exclusivity. In any specific case, this may speed approval of subsequent ANDA applicants and, therefore, competition in the marketplace. However, a relatively broad trigger for 180-day exclusivity could diminish the value of 180-day exclusivity to ANDA applicants, and thus it might also reduce the incentive for ANDA applicants to challenge an innovator's patents. A relatively narrow interpretation, such as the "holding-on-the-merits" standard, may slow approval of subsequent ANDAs and competition in a specific case. It could, however, make exclusivity more valuable, and thus make patent challenges more common overall. In any event, the legislative history offers little if any guidance as to which interpretation Congress might have preferred, and thus it is appropriate to apply the interpretation most consistent with the plain language of the provision. *See, e.g., Teva*, 410 F.3d at 54.

In the absence of clear Congressional intent to promote another policy objective, the agency considers clarity and certainty of critical importance. Because of the huge financial consequences that result from gaining or losing six months of ANDA marketing exclusivity, drug companies have creatively construed the FDCA and relevant court decisions to gain whatever marketing advantage they can. This dynamic is demonstrated with remarkable clarity by Apotex's and Teva's having taken legal positions with respect to the Apotex-Bristol dismissal that are diametrically opposed to their positions in the original *Teva* litigation during 1999 and 2000. This change of positions is not surprising because their roles are reversed: with respect to pravastatin, they each occupy the seat the other occupied with respect to ticlopidine. Indeed, the parties' (as well as the Generic Pharmaceutical Association's) disparate policy arguments for and against easier triggering at different times underscores that there may be no clearly preferable position from a policy perspective. *See, e.g., Teva Pharms. USA, Inc. v. FDA*, No. 05-1469 (D.D.C.) (Opp. of Intervenor-Defendant Apotex Inc. to Mot. of Generic Pharmaceutical Ass'n for Leave to File Brief as *Amicus Curiae*, at 2-4, filed Sept. 9, 2005) (noting that the Generic Pharmaceutical Association has made policy arguments both for and against a broad interpretation of the court decision trigger in different cases).

The stipulated order dismissing the Apotex-Bristol case could reasonably be viewed as an effort to tailor a dismissal order to satisfy the estoppel standard discussed in *Teva I*. It includes a statement on its face that Bristol had committed not to sue Apotex for patent infringement. It expressly states that the case is dismissed for lack of subject matter jurisdiction on the basis of Bristol's assurances. Nevertheless, Teva challenged the agency's determination on multiple grounds, including whether Bristol's statements had estoppel effect and whether the order constituted a decision of a court as a matter of federal civil procedure law.[9]

FDA's experience suggests that drug companies will continue to litigate over exclusivity issues whenever the potential financial rewards are sufficiently high. Were FDA to adopt a standard less objective and clear than the "holding-on-the-merits" standard, the opportunities for disputes regarding the tripping of the court decision trigger would increase. Further, it seems reasonable to assume that applicants are more likely to conclude that their chances of success in court are better in cases concerning patentee estoppel because of FDA's lack of expertise on this issue.

It is in the public's interest, as well as FDA's own interest, to have exclusivity triggering determinations governed by a legal regime that is clear and easily administered. Encouraging highly-interested and well-financed litigants to pursue ever-finer distinctions, ever farther removed from the language of the statute and from its purposes, does not advance the public's interest. It offers no guarantee of more rapid generic drug approvals, only a high likelihood of delay due to litigation, and the prospect that this area of law will remain unnecessarily unstable, thus undermining marketplace certainty and interfering with business planning and investment.

C. Application of FDA's Interpretation to the Apotex-Bristol Dismissal

Under FDA's interpretation, it is clear that the July 23, 2004, stipulated order dismissing the Apotex-Bristol declaratory judgment action is not a court decision "holding" that the subject patents are invalid, not infringed, or unenforceable. Nowhere on the face of the order is there such a determination by the court regarding any of the patents at issue. Even if Bristol's assurances to Apotex, incorporated into the dismissal order, were later determined by a court to estop Bristol from suing Apotex for infringement, the July 23, 2004 dismissal itself does not contain a holding on the merits

---

[9] The agency's brief on appeal to the *Teva III* court indicates the potentially myriad complexities of attempting to apply an estoppel-based standard:

> The considerations that the district court's decision make crucial – whether the dismissal for lack of jurisdiction resulted from a motion or a stipulation, whether the dismissal was effected under one procedural rule or another, whether the dismissal recites that the court found "good cause" for it, whether the court considered papers beyond the motion or stipulation itself, whether the court held a hearing, and the like . . . bear no relationship either to whether the decision "hold[s] the patent ... to be invalid or not infringed" . . . .

Br. for the Federal Appellants at 54 (filed Dec. 22, 2005).

of patent invalidity, noninfringement, or unenforceability — the issues specified by Congress in the statute (and FDA by regulation). Indeed, the dismissal order makes clear that the case was dismissed for procedural reasons (lack of subject matter jurisdiction) based on Bristol's representations without a holding on the merits of Apotex's declaratory judgment patent claims.

FDA has thus concluded that 180-day exclusivity for pravastatin was not triggered by the July 23, 2004 dismissal. Absent a material change in circumstances, FDA intends to approve only those ANDAs eligible for 180-day exclusivity for pravastatin when the '227 patent (including its period of pediatric exclusivity) expires on April 20, 2006. Approvals of all other pravastatin ANDAs will be delayed for 180 days after exclusivity has been triggered.[10]

III. Conclusion

FDA interprets the court decision trigger provision to require a decision of a court that on its face evidences a holding on the merits of patent noninfringement, invalidity, or unenforceability. The July 23, 2004, Apotex-Bristol dismissal does not contain such a holding. FDA therefore denies Apotex's request for an agency determination that 180-day exclusivity for pravastatin has been triggered and run.

Sincerely,

/s/ "Gary Buehler"

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

[10] Apotex asserted that the Apotex-Bristol dismissal applied to the 10 mg, 20 mg, 40 mg, and 80 mg strengths of pravastatin. Because FDA has determined that the Apotex-Bristol dismissal does not qualify as a court decision trigger for any strength of pravastatin, FDA need not decide (and this decision should not be construed as deciding) whether the dismissal order encompassed all four strengths.

EXHIBIT B

Westlaw.

--- F.3d ----

--- F.3d ----, 2006 WL 3289050 (C.A.D.C.), 80 U.S.P.Q.2d 1764

(Cite as: --- F.3d ----)

H

Briefs and Other Related Documents

Ranbaxy Laboratories Ltd. v. LeavittC.A.D.C.,2006.

United States Court of Appeals,District of Columbia Circuit.

RANBAXY LABORATORIES LIMITED, et al., Appellees

v.

Michael O. LEAVITT, Secretary of Health and Human Services, et al., Appellants.

No. 06-5154.

Argued Sept. 12, 2006.

Decided Nov. 14, 2006.

Background: Generic drug manufacturer brought action against Secretary of Health and Human Services and Food and Drug Administration (FDA) to challenge regulation after FDA delisted drug patent and deprived manufacturer of period of market exclusivity. The United States District Court for the District of Columbia, Richard W. Roberts, J., entered judgment in favor of manufacturer. FDA appealed.

Holding: The Court of Appeals, Ginsburg, Chief Judge, held that FDA regulation making manufacturer of generic drug ineligible for 180 days of market exclusivity if the holder of the new drug application seeks to delist the patent, rather than to litigate validity or infringement, is unlawful.

Affirmed.

[1] Statutes 361 ⇐219(6.1)

361 Statutes
361VI Construction and Operation
361VI(A) General Rules of Construction
361k213 Extrinsic Aids to Construction
361k219 Executive Construction
361k219(6) Particular Federal Statutes
361k219(6.1) k. In General. Most Cited Cases

The Court of Appeals reviews the Food and Drug Administration's (FDA) interpretation of the Federal Food, Drug, and Cosmetic Act (FDCA) it administers under the two-step analysis in *Chevron*: (1) the Court first asks whether the Congress has directly spoken to the precise question at issue, and (2) if the statute is silent or ambiguous with respect to the specific issue, the question is whether the agency's answer is based on a permissible construction of the statute. Federal Food, Drug, and Cosmetic Act, § 1 et seq., 21 U.S.C.A. § 301 et seq.

[2] Health 198H ⇐319

198H Health
198HI Regulation in General
198HI(E) Drugs; Medical Devices and Instruments
198Hk315 Applications and Approvals
198Hk319 k. Generic and Orphan Drugs; Market Exclusivity. Most Cited Cases

Food and Drug Administration (FDA) regulation making manufacturer of generic drug ineligible for 180 days of market exclusivity if the holder of the new drug application seeks to delist the patent, rather than to litigate validity or infringement, is inconsistent with statute giving the period of market exclusivity; the statute does not require litigation to preserve a generic applicant's eligibility for exclusivity, and by reducing the certainty of receiving a period of marketing exclusivity, the FDA's delisting policy diminishes the incentive for a manufacturer of generic drugs to challenge a patent listed in the Orange Book in the hope of bringing to market a generic competitor for an approved drug without waiting for the patent to expire. Federal Food, Drug, and Cosmetic Act, § 505(j)(2)(A)(vii), (5)(B)(iii, iv), 21 U.S.C.A. § 355(j)(2)(A)(vii), (5)(B)(iii, iv); 21 C.F.R. § 314.94(a)(12)(viii)(B).

[3] Health 198H ⇐319

198H Health
198HI Regulation in General
198HI(E) Drugs; Medical Devices and Instruments
198Hk315 Applications and Approvals
198Hk319 k. Generic and Orphan Drugs;

Market Exclusivity. Most Cited Cases
The Food and Drug Administration (FDA) may not change the incentive structure adopted by Congress for benefit of generic drug manufacturer, for the agency is bound not only by the ultimate purposes Congress has selected, but by the means it has deemed appropriate, and prescribed, for the pursuit of those purposes. Federal Food, Drug, and Cosmetic Act, § 505, 21 U.S.C.A. § 355.
West CodenotesHeld Invalid21 C.F.R. § 314.94(a)(12)(viii)(B)

Appeal from the United States District Court for the District of Columbia (No. 05cv01838).

Howard S. Scher, Attorney, U.S. Department of Justice, argued the cause for appellants. With him on the briefs were Peter D. Keisler, Assistant Attorney General, Kenneth L. Wainstein, U.S. Attorney, Douglas N. Letter, Attorney, and Eric M. Blumberg, Deputy Chief Counsel, U.S. Department of Health and Human Services. Drake S. Cutini, Attorney, U.S. Department of Justice, entered an appearance.
Simon E. Dance was on the brief for amicus curiae Blue Cross & Blue Shield Association, Inc. in support of appellants.
Carmen M. Shepard argued the cause for appellees Ranbaxy Laboratories Limited, et al. With her on the brief were Kate C. Beardsley and William B. Schultz.
Jay P. Lefkowitz argued the cause for appellee Teva Pharmaceuticals, USA, Inc. With him on the brief were John C. O'Quinn and Michael D. Shumsky.
Theodore Case Whitehouse was on the brief for amicus curiae Generic Pharmaceutical Association in support of appellees.

Before: GINSBURG, Chief Judge, and GRIFFITH and KAVANAUGH, Circuit Judges.

Opinion for the Court filed by Chief Judge GINSBURG.GINSBURG, Chief Judge.
***1** The Hatch-Waxman Amendments to the Food, Drug, & Cosmetic Act provide a period of marketing exclusivity to the first drug manufacturer that either successfully challenges a patent listed by the Food and Drug Administration for an approved, branded drug and markets an approved generic version of that drug or prevails in litigation establishing that the patent is valid or not infringed. Ranbaxy Laboratories Limited and Ivax Pharmaceuticals, Inc., the latter since acquired by Teva Pharmaceuticals, USA, Inc., applied for approval of drugs to compete with an approved drug manufactured by Merck & Co. and challenged two patents covering it. Thereafter, at Merck's request, the FDA removed the challenged patents from the "Orange Book," its listing of patents covering approved drugs, thereby depriving the generic manufacturers of an opportunity to have a period of marketing exclusivity.

Ranbaxy and Teva each filed a "citizen petition" asking the FDA to relist the two patents. The FDA denied the petitions because Merck had not sued Ranbaxy or Teva for patent infringement. Ranbaxy and Teva then repaired to the district court, which entered a summary judgment for the plaintiffs, and the FDA appealed.

We hold the FDA's requirement that a generic manufacturer's patent challenge give rise to litigation as a condition of retaining exclusivity when a patent is delisted is inconsistent with the Act, which provides that the first generic manufacturer to file an approved application is entitled to exclusivity when it either begins commercially to market its generic drug or is successful in patent litigation. Accordingly, we affirm the judgment of the district court.

I. Background

Before marketing a new "branded" drug, the manufacturer must file with the FDA a New Drug Application (NDA), including evidence the drug is safe and effective, and the identifying number and expiration date of any patent or patents covering the drug. 21 U.S.C. § 355(a)-(b)(1). When it approves the NDA, the FDA must publish the patent information, *id.* § 355(b)(1), (c)(2), which it does in *Approved Drug Products with Therapeutic Equivalence Evaluations,* better known as the Orange Book.

Before marketing a "generic drug," which is bioequivalent to a branded drug previously approved pursuant to an NDA, the manufacturer may submit an Abbreviated New Drug Application (ANDA). Unlike an NDA, an ANDA need not contain evidence of the

drug's safety or efficacy. *See* 21 U.S.C. § 355(j)(2). Each ANDA, however, must contain:

a certification ... with respect to each patent which claims [a drug or a method of using a drug listed in the Orange Book] for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c) of this section-

(I) that such patent information has not been filed,

(II) that such patent has expired,

(III) [that] such patent will expire [on a specified date], or

***2** (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted[.]

Id. § 355(j)(2)(A)(vii). The Act rewards the first manufacturer to file an approved ANDA containing the certification in paragraph IV by giving it a 180-day period of marketing exclusivity, which begins with the earlier of the applicant's first commercial marketing of the generic drug or when the applicant prevails in a suit over infringement or the validity of the patents covering the branded drug. *Id.* § 355(j)(5)(B)(iii)-(iv).[FN*]

When a patent is removed from the Orange Book (or, in the parlance of the agency is "delisted"), the FDA by regulation requires the sponsor of the corresponding ANDA to delete its paragraph IV certification with respect to the delisted patent. 21 C .F.R. § 314.94(a)(12)(viii)(B).[FN*] If no patent covering the branded drug remains listed, then the generic applicant must file a paragraph I certification, and the FDA treats the ANDA as though it had never contained a paragraph IV certification. As a result, the generic applicant that was first to file an approved application does not get the 180-day period of exclusivity. *See id.*

Merck, which marketed simvastatin under the brand name Zocor®, submitted to the FDA information with respect to three patents covering the drug: U.S. Patent Nos. 4,444,784 (the 784 Patent), RE 36,481 (the 481 Patent), and RE 36,520 (the 520 Patent). Teva and Ranbaxy each filed an ANDA to market generic simvastatin. The two ANDAs-both of which were eligible for a 180-day period of marketing exclusivity because they involved different dosages-each contained a paragraph IV certification with respect to the 481 and 520 Patents. With respect to the 784 Patent, Ranbaxy and Teva each filed a paragraph III certification that it would expire in December 2005.

Merck, however, did not sue Ranbaxy or Teva for patent infringement based upon their paragraph IV certifications. Instead, before their ANDAs were approved, Merck asked the FDA to delist the 481 and 520 Patents from the Orange Book, which the agency did in 2004. Consequently, under 21 C.F.R. § 314.94(a)(12)(viii)(B), Ranbaxy and Teva were required to delete the paragraph IV certifications from their ANDAs and thereby lost their eligibility for a period of marketing exclusivity. Ranbaxy and Teva accordingly petitioned the FDA to relist the 481 and 520 Patents in the Orange Book, restore their period of exclusivity, and refrain from approving any other manufacturer's ANDA for generic simvastatin until their period of exclusivity expired.

In a letter ruling denying the petitions, the FDA said it had considered three possible methods of handling the request of a manufacturer with an approved NDA to delist a patent. First, the FDA could always delist the patent, but that could unfairly deny a period of marketing exclusivity to the generic manufacturer that would later be the first to file an approved ANDA by depriving it of the opportunity to prevail in patent litigation. Second, it could refuse to delist the patent only if a generic manufacturer had filed an ANDA containing a paragraph IV certification with respect to the patent, but the agency rejected that possibility on the ground that "eligibility for exclusivity does not vest with a patent challenge," that is, upon the filing of a paragraph IV certification. Finally, the FDA could delist a patent only if a generic manufacturer had filed an ANDA containing a paragraph IV certification with respect to the patent *and* the NDA holder had not filed a lawsuit to contest the certification. The FDA chose the last option on the ground that it best balanced, on the one hand, the procompetitive effect of the incentive for a generic drug manufacturer to be the first to challenge a patent listed in the Orange Book and thereby introduce generic competition to a branded drug and, on the other, the loss of competition among generic manufacturers

caused by the 180-day period of marketing exclusivity for the first to file an approved ANDA containing a paragraph IV certification.

***3** Ranbaxy and Teva then brought this action in the district court, which held the FDA's delisting policy was inconsistent with the Act because, by requiring the first generic manufacturer that filed a paragraph IV certification to remove that certification before its ANDA could be approved, it deprived the generic applicant of the opportunity to obtain a period of exclusivity pursuant to 21 U.S.C. § 355(j)(5)(B)(iv)(I) by commercially marketing its drug. The court entered judgment for Ranbaxy and Teva and the FDA appealed.

II. Analysis

[1] We review the FDA's interpretation of the Act it administers under the two-step analysis in *Chevron, U.S.A. Inc. v. NRDC*, 467 U.S. 837, 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984). *See Teva Pharm. Indus. Ltd. v. Crawford*, 410 F.3d 51, 53 (D.C.Cir.2005) (reviewing under *Chevron* FDA ruling on citizen petition). First, we ask whether the "Congress has directly spoken to the precise question at issue." *Chevron*, 467 U.S. at 842. "If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Id.* at 842-43. If, however, "the statute is silent or ambiguous with respect to the specific issue, the question ... is whether the agency's answer is based on a permissible construction of the statute." *Id.* at 843.

[2] Ranbaxy and Teva claim this case can be resolved at *Chevron* step one. Ranbaxy argues that 21 U.S.C. § 355(j)(5)(B)(iv) on its face entitles the company to a period of marketing exclusivity, and Teva contends the FDA's distinction between filers of paragraph IV certifications that are sued and those that are not has no basis in the Act.

Under the rubric of *Chevron* step two, Ranbaxy and Teva argue the FDA's policy of delisting a patent in the absence of litigation is unreasonable for a variety of reasons. Upon examination, however, we believe their arguments are better considered at *Chevron* step one. More specifically, Teva contends the requirement of litigation is inconsistent with the text and structure of the statute and with its purpose, as elucidated in circuit precedent. Here it refers in particular to *Mova Pharmaceutical Corp. v. Shalala*, 140 F.3d 1060, 1069 (D.C.Cir.1998), in which we held 21 U.S.C. § 355(j)(5)(B)(iv) precludes the FDA from conditioning marketing exclusivity upon the first to file an ANDA prevailing in patent litigation, and to *Purepac Pharmaceutical Co. v. Friedman*, 162 F.3d 1201, 1204-05 (D.C.Cir.1998), in which we held the FDA reasonably gave a period of marketing exclusivity to the first generic drug manufacturer to file a paragraph IV certification even though it never litigated the infringement or validity of the patent. Based upon these cases, Teva argues that the Act precludes the FDA from predicating exclusivity upon a patent infringement suit being brought by the NDA holder. Ranbaxy suggests the FDA's policy is inconsistent with the Act for two other reasons: first, the policy diminishes the incentive the Congress provided for a generic manufacturer to challenge a patent by reducing the certainty of its getting a period of marketing exclusivity; and second, by balancing anew the costs and benefits of the exclusivity provided by the Congress, the policy exceeds the authority of the agency.

***4** In response, the FDA argues that its regulation requiring the filer of an ANDA to amend its certification when a patent is delisted, 21 C.F.R. § 314.94(a)(12)(viii)(B), is not inconsistent with the Act because 21 U.S.C. § 355(j)(5) is silent with regard to the withdrawal of patent information previously submitted for listing in the Orange Book. The FDA points out that a generic applicant's exclusivity does not vest upon the filing of a paragraph IV certification; otherwise, it asserts, the filer's eligibility for exclusivity would not be lost when, for example, the patent subject to the paragraph IV certification expires, *see Dr. Reddy's Labs., Inc. v. Thompson*, 302 F.Supp.2d 340, 354-55 (D.N.J.2003) (holding FDA reasonably interpreted 21 U.S.C. § 355(j)(5)(B)(iv) not to extend exclusivity to ANDA approved after patent had expired), or the generic applicant loses in patent litigation, *see Mylan Labs., Inc. v. Thompson*, 389 F.3d 1272, 1282-84, 1283 n. 10 (D.C.Cir.2004).

The FDA then argues its policy is reasonable because

it allows an NDA holder to eliminate the patent as a barrier to approval of an ANDA when that patent does not cover the drug or method of use for which it was listed in the Orange Book. At the same time the policy preserves the ministerial nature of the FDA's role in maintaining the patent listings in the Orange Book because, when an NDA holder asks it to delist a patent, the agency need not determine whether the NDA holder is acting strategically to deny the generic applicant a period of marketing exclusivity or the patent actually does not cover the drug for which it was submitted-the interpretation of patent listings being outside the agency's expertise.

The "precise question at issue" at *Chevron* step one is, in our view, whether the FDA may delist a patent upon the request of the NDA holder after a generic manufacturer has filed an ANDA containing a paragraph IV certification so that the effect of delisting is to deprive the applicant of a period of marketing exclusivity. The Congress unquestionably provided two ways in which a generic drug manufacturer may begin a 180-day period of exclusivity: (1) by marketing its drug commercially, or (2) by convincing a court that the patent subject to its paragraph IV certification is either invalid or not infringed. 21 U.S.C. § 355(j)(5)(B)(iv). When the NDA holder asks the FDA to delist the patent, however, the FDA's policy of acquiescence prevents the generic manufacturer that has filed an ANDA containing a paragraph IV certification from beginning its period of exclusivity.

We have previously rejected at *Chevron* step one the FDA's attempt to add to the statutory requirements for exclusivity by making it contingent upon success in litigation. In *Mova* we held the "successful defense" rule, which afforded exclusivity only to the generic applicant that both filed the first approved ANDA with a paragraph IV certification and successfully defended an infringement suit, was inconsistent with the text and structure of the Act because it permitted the FDA to approve a later ANDA before either the first to file began to market its drug commercially or a court held the subject patent invalid or not infringed; the rule thereby "[wrote] the commercial-marketing trigger out of the statute." 140 F.3d at 1069-70. Later we upheld as reasonable at *Chevron* step two the FDA's decision to grant a generic applicant a period of marketing exclusivity even though its paragraph IV certification did not result in litigation precisely because the FDA's approach "basically duplicat[ed] the statute." *Purepac*, 162 F.3d at 1204-05.

***5** Not only does the statute not require litigation to preserve a generic applicant's eligibility for exclusivity, as those precedents make clear; such a requirement is inconsistent with the structure of the statute because, if the patent is delisted before a pending ANDA is approved, then the generic manufacturer may not initiate a period of marketing exclusivity. The FDA's observation that the generic applicant's right to a period of marketing exclusivity does not vest upon its filing a paragraph IV certification is beside the point, which is that the Act makes the generic applicant eligible for exclusivity while the FDA's policy makes it ineligible for exclusivity. FN*

[3] In addition, the FDA's policy allows an NDA holder, by delisting its patent, to deprive the generic applicant of a period of marketing exclusivity. By thus reducing the certainty of receiving a period of marketing exclusivity, the FDA's delisting policy diminishes the incentive for a manufacturer of generic drugs to challenge a patent listed in the Orange Book in the hope of bringing to market a generic competitor for an approved drug without waiting for the patent to expire. The FDA may not, however, change the incentive structure adopted by the Congress, for the agency is bound "not only by the ultimate purposes Congress has selected, but by the means it has deemed appropriate, and prescribed, for the pursuit of those purposes." *MCI Telecomms. Corp. v. AT & T Co.*, 512 U.S. 218, 231 n. 4, 114 S.Ct. 2223, 129 L.Ed.2d 182 (1994). Therefore, we hold unlawful the FDA's policy requiring that the first filer of a paragraph IV certification be sued in order to preserve its statutory exclusivity when the NDA holder seeks to delist the patent rather than to litigate.

III. Conclusion

In sum, the FDA's policy conditioning a generic applicant's period of marketing exclusivity upon the generic applicant being sued for patent infringement by the NDA holder is inconsistent with the text and structure of the Act and, because it diminishes the in-

centive the Congress gave manufacturers of generic drugs, is inconsistent with the purpose of the Act. Therefore, we conclude the FDA improperly denied Ranbaxy and Teva a period of marketing exclusivity by delisting Merck's patents. For the foregoing reasons, the judgment of the district court is

Affirmed.

> FN* If the [ANDA] contains a certification described in [paragraph] (IV) ... and is for a drug for which a previous [ANDA] has been submitted under this subsection [containing] such a certification, the [ANDA] shall be made effective not earlier than one hundred and eighty days after-
> (I) the date the Secretary receives notice from the applicant under the previous [ANDA] of the first commercial marketing of the drug under the previous [ANDA], or
> (II) the date of a decision of a court in an action ... holding the patent which is the subject of the certification to be invalid or not infringed,
> whichever is earlier.
> *Id.* § 355(j)(5)(B)(iv).
> This provision was amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003(MMA), Pub.L. No. 108-173, tit. XI, § 1102(a)(2)(D)(i)(I)(bb)(CC), (a)(2)(D)(ii), 117 Stat.2066, 2457-59 (Dec. 8, 2003) (codified at 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(CC), (j)(5)(D)(ii) (2003)). The decisions of the FDA and of the district court were made pursuant to the Act as it stood before the MMA and, because the MMA was not made retroactive, § 1102(b)(1), 117 Stat. at 2460, this decision is also geared to the Act pre-MMA.
>
> FN* If a patent is removed from the [Orange Book], any applicant ... who has made a certification with respect to such patent shall amend its certification. The applicant shall certify ... that no patents [required to be listed in the Orange Book] claim the drug or, if other relevant patents claim the drug, shall amend the certification to refer only to those relevant patents .... Once an amendment ... has been submitted, the application will no longer be considered to be one containing a [paragraph IV certification].
> 21 C.F.R. § 314.94(a)(12)(viii)(B).
>
> FN* We need not address the question of patent expiration in this case. We note, however, as Ranbaxy and Teva acknowledged at oral argument, the text and structure of the statute suggest a distinction between expiration and delisting such that the first generic applicant may no longer retain exclusivity when the patent has expired. *See* 21 U.S.C. § 355(j)(5)(B)(i); *see also Dr. Reddy's Labs.*, 302 F.Supp.2d at 354-55.

C.A.D.C.,2006.
Ranbaxy Laboratories Ltd. v. Leavitt
--- F.3d ----, 2006 WL 3289050 (C.A.D.C.), 80 U.S.P.Q.2d 1764

Briefs and Other Related Documents (Back to top)

- 2006 WL 1757180 (Appellate Brief) Brief for the Appellants (Jun. 21, 2006) Original Image of this Document with Appendix (PDF)
- 06-5154 (Docket) (May 25, 2006)

END OF DOCUMENT

EXHIBIT C

LEXSEE 2005 US DIST LEXIS 39475

DEY, L.P., Plaintiff, v. EON LABS, INC., Defendant. AND RELATED COUNTER-CLAIMS.

CASE NO. SACV 04-00243 CJC (FMOx)

UNITED STATES DISTRICT COURT FOR THE CENTRAL DISTRICT OF CALIFORNIA, SOUTHERN DIVISION

2005 U.S. Dist. LEXIS 39475

December 22, 2005, Decided
December 22, 2005, Filed

COUNSEL: [*1] For Dey LP, Plaintiff: Alan Peter Block, Hazim H Ansari, Kevin I Shenkman, Khannan Suntharam, Marc Morris, Roderick G Dorman, Hennigan Bennett and Dorman, Los Angeles, CA; James P Doyle, Cohen Pontani Lieberman and Pavane, New York, NY.

For Eon Labs Inc, Defendant: David P Badanes, Martin B Pavane, William A Alper, James P Doyle, Cohen Pontani Lieberman and Pavane, New York, NY; John A Scillieri, Seldon & Scillieri, Los Angeles, CA; Robert A Seldon, Robert A Seldon Law Offices, Los Angeles, CA.

For Eon Labs Inc, Counter Claimant: John A Scillieri, Robert A Seldon, Seldon and Scillieri, Los Angeles, CA; Martin B Pavane, Cohen Pontani Lieberman and Pavane, New York, NY.

For Dey LP, Counter Defendant: James P Doyle, Cohen Pontani Lieberman and Pavane, New York, NY; Kevin I Shenkman, Khannan Suntharam, Marc Morris, Roderick G Dorman, Alan Peter Block, Hennigan Bennett and Dorman, Los Angeles, CA.

For Eon Labs Inc, Counter Claimant: John A Scillieri, Robert A Seldon, Seldon and Scillieri, Los Angeles, CA; Martin B Pavane, William A Alper, Cohen Pontani Lieberman and Pavane, New York, NY.

For Dey LP, Counter Defendant: Kevin I Shenkman, Marc Morris, Hennigan Bennett [*2] and Dorman, Los Angeles, CA.

For Eon Labs Inc, Counter Claimant: John A Scillieri, Robert A Seldon, Seldon and Scillieri, Los Angeles, CA.

JUDGES: CORMAC J. CARNEY, UNITED STATES DISTRICT JUDGE.

OPINION BY: CORMAC J. CARNEY

OPINION:

ORDER DENYING PLAINTIFF'S MOTION FOR RECONSIDERATION OF THIS COURT'S NOVEMBER 4, 2005 ORDER GRANTING DEFENDANT'S MOTION TO SHORTEN 30-MONTH STATUTORY STAY ON FDA APPROVAL OF DEFENDANT'S ABBREVIATED NEW DRUG APPLICATION

Plaintiff and Counterdefendant Dey, L.P. ("Dey") moves pursuant to *Federal Rule of Civil Procedure 60(b)* for reconsideration of this Court's Order issued November 4, 2005, granting a motion filed by Defendant and Counterclaimant Eon Labs, Inc. ("Eon") to shorten the automatic 30-month statutory stay of FDA approval on Eon's Abbreviated New Drug Application under *21 U.S.C. § 355(j)(5)(B)(iii)*. In its Order, the Court ruled that Dey had failed to reasonably cooperate in expediting this action by acting unreasonably in identifying the individuals who invented the subject matter claimed in the patent in suit. n1 Because Dey has not shown that reconsideration is warranted by new evidence [*3] or the need to correct a clear error or prevent manifest injustice, its motion for reconsideration is DENIED. A party suing under a patent has an obligation to conduct a good-faith investigation into inventorship. While *35 U.S.C. § 256* allows a patentee to move to correct innocent mistakes in inventorship, this right does not excuse the patentee from making an informed decision on the issue at the time it files its patent, when it initiates litigation, and during the course of that litigation. In this case, Dey cannot continue to reap $ 200,000,000 n2 per year from its patent, free from generic competition, where it has failed and continues to fail to take a reasonable position on the critical issue of inventorship.

n1 The Court also found that Dey failed to reasonably cooperate in expediting this action by not timely disclosing a 2003 study involving Combivent MDI, a drug solution which Eon contends is prior art to the *842 patent*, and producing after the close of discovery certain documents pertaining to the study.

n2 Eon's Memorandum in Support of its Motion to Shorten 30-Month Statutory Stay, p. 2.

[*4]

A. Background

This patent infringement action involves Dey's *U.S. Patent No. 6,632,842* B2 ("the *842 patent*"), and Eon's attempts to market a generic version of a commercial drug described therein. The *842 patent* does not claim the drug, but rather "a method of reducing medication error and enhancing therapeutic compliance of an individual suffering from chronic obstructive pulmonary disease," ("COPD"), a lung disease common in smokers. (Exhibit 1 to Complaint.) The claimed method sets forth a procedure by which COPD patients are administered single-dose containers containing a combination solution consisting of albuterol and ipratropium bromide and meeting certain other criteria n3 (the "administering step"). (Exhibit 1 to Complaint.) In addition to the administering step, the *842 patent*'s claims require that patients be provided with specific prescribing, contraindication, and adverse reaction information (the "providing step"). (*Id.*) Dey currently markets the albuterol/ipratropium bromide solution described in the *842 patent* under the name "DuoNeb." (Complaint, P 6.)

n3 For instance, the claims prescribe that the volume of the solution is about 3 ml and that it be sterile, BAC free, satisfy certain stability criteria and contain specified amounts of ipratropium bromide and albuterol. (MFR, p. 12; Marc Morris Decl., P 10, Exh. D thereto.)

[*5]

1. Dey's Development of the Patented Subject Matter

The *842 Patent* was the culmination of a long development process by Dey. In the 1990s, Dey began developing an inhalation solution that had many characteristics of the solution described in the *842 patent*'s administering claims, but with some differences. (Motion for Reconsideration, "MFR," pp. 12-13.) A number of individuals employed by Dey contributed to the development of the product. (*Id.*, p. 13.) Dey was unable to obtain FDA approval for the original product, despite years of trying. (*Id.*)

In the late 1990s several new people came to work for Dey, and made changes to the inhalation solution and its delivery system. Among other things, these new employees contributed to the definition of "albuterol" contained in the *842 patent* and made the product "stable" by using a foil overwrap which is described in the patent. (MFR, pp. 13-14.) Dey received FDA approval for the inhalation solution, "DuoNeb," in the late 1990s. Dey subsequently filed a patent application with the U. S. Patent and Trademark Office ("USPTO"), and, on December 28, 2001 filed a "continuation in part" ("CIP") application. n4 (MFR, p. 5, n.6.) [*6] The *842 Patent* was issued on October 14, 2003, based on the CIP application. (*Id.*; Complaint, P 9.) By the time Dey filed the applications leading to the *842 patent*'s issuance, the developers who had developed the inhalation solution in the early 1990s no longer worked for Dey. (MFR, p. 14.)

n4 "A CIP application contains subject matter from a prior application and may also contain additional matter not disclosed in the prior application." *Augustine Medical, Inc. v. Gaymar Industries, Inc., 181 F.3d 1291, 1302, 50 U.S.P.Q. 2d 1900, 1908 (Fed. Cir. 1999) (citing Waldemar Link v. Osteonics Corp., 32 F.3d 556, 558, 31 U.S.P.Q. 2d 1855, 1857 (Fed. Cir. 1994))*. Different claims in a CIP application may receive different filing dates. *Id.* The part of a CIP application that duplicates material contained in the original application (and specified in the original in a manner that satisfies the description requirement of *35 U.S.C. § 112*) is credited with the filing date of the original application. *Therma-Tru Corp. v. Peachtree Doors, Inc., 44 F.3d 988, 992, 33 U.S.P.Q. 2d 1274, 1276 (Fed. Cir. 1995)*. The part of the CIP application containing new material is treated as a new application and is given the CIP application's filing date. *Augustine, 181 F.3d at 1302, 50 U.S.P.Q. at 1908.*

[*7]

2. Eon's Abbreviated New Drug Application

In early 2004, Eon sought to market a generic version of DuoNeb. Pursuant to *21 U.S.C. § 355(j)*, Eon filed an Abbreviated New Drug Application ("ANDA") with the FDA to obtain approval to engage in the commercial manufacture, use, and sale of a generic copy of DuoNeb for the treatment of symptoms of COPD. n5

The Drug Price Competition and Patent Term Restoration Act of 1984, also called the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act, Pub. L. No. 98-417, 98 Stat. 1585, codified in relevant part at *21 U.S.C. § 355*, allows a generic drug manufacturer such as Eon to file an ANDA, in lieu of a full New Drug Application, regarding the generic drug's safety and efficacy. *21 U.S.C. § 355(j)*. By filing an ANDA, the generic manufacturer avoids the need to submit full information regarding the generic drug, and may instead rely on safety and efficacy studies previously submitted to the FDA by the manufacturer of an already-listed drug (the "pioneer manufacturer"), so long as the ANDA applicant provides information showing that the generic drug is bioequivalent [*8] to the listed drug and is identical to it in certain other ways. *21 U.S.C. § § 355(j)(1); 355(j)(2)(A)(i)-(v)*.

n5 The Federal Food, Drug, and Cosmetic Act, *21 U.S.C. § § 301 et seq.*, prohibits the introduction into interstate commerce of any drug unless an application has been filed with respect to the drug and been approved by the FDA. *21 U.S.C. § 355(a)*.

A pioneer manufacturer that holds a New Drug Application ("NDA") must notify the FDA of all patents that "claim[] the drug for which the [NDA] applicant submitted the application or which claim[] a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." *21 U.S.C. § § 355(b)(1); (c)(2)*. These patents are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, or the "Orange Book." *Andrx Pharmaceuticals, Inc. v. Biovail Corp., 276 F.3d 1368, 1371, 61 U.S.P.Q. 2d 1414, 1415 (Fed. Cir. 2002)*. [*9]

An ANDA applicant must make one of the following four certifications as to each patent that claims either the listed drug or a use for the listed drug for which the ANDA applicant seeks approval and for which information was required to be filed under *21 U.S.C. § 355 subsections (b)* or *(c)*: (I) that such patent information has not been filed; (II) that the patent has expired, (III) of the date on which the patent will expire; or (IV) that the patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the ANDA is submitted. *21 U.S.C. § 355(j)(2)(A)(vii)(I-IV)*. When the generic manufacturer makes a subpart (IV) certification, the ANDA applicant must notify the NDA holder and explain the basis for its subpart IV certification. *21 U.S.C. § 355(j)(2)(B)(i)-(iv); 21 C.F.R. 314.95(c)(6)*. If the NDA holder sues the ANDA applicant for patent infringement within 45 days of the notification, the FDA may not approve the ANDA until the earlier of thirty months after the patentee's receipt of notice or entry of a court judgment reflecting a determination that [*10] the patent is invalid or not infringed. *21 U.S.C. § 355(j)(5)(B)(iii)*. The court in which the infringement suit is pending may, however, lengthen or shorten the stay on FDA approval if "either party to the action fail[s] to reasonably cooperate in expediting the action." *21 U.S.C. § 355(j)(5)(B)(iii)*.

Here, Eon made a subpart IV certification in connection with its ANDA, stating that Dey's *842 patent* was invalid or would not be infringed by Eon's COPD product. Dey received that letter on January 20, 2004. (Complaint, P 8.) Within 45 days of receiving the letter, on March 3, 2004, Dey sued Eon for patent infringement. As Dey sued Eon within 45 days of being notified of the subpart IV certification, the 30-month stay is now in effect.

3. Eon's Motion to Terminate the 30-Month Stay on FDA Approval

On September 22, 2005, Eon filed a motion with this Court to terminate the 30-month stay on the basis that Dey had failed to reasonably cooperate in expediting this action by, among other things, repeatedly changing its position on the inventorship of the *842 patent*, and failing to produce in discovery documents related to a 2003 study [*11] comparing DuoNeb to a drug that Eon claims is prior art to the *842 patent*. Eon asserted that neither of the two individuals listed as inventors on the *842 patent*, Imtiaz Chaudry and Partha Banerjee, worked for Dey during Dey's initial development of the inhalation solution described in the *842 patent* in the mid-1990s. Eon pointed out that, in 2004, Dey submitted and subsequently withdrew a petition to the USPTO to correct inventorship by adding Charles Rice as a named inventor. (Eon's Points and Authorities re Shortening Stay, p. 6.) After Dey withdrew the petition, Dey stated that it planned to ask the Court, at the conclusion of evidence at trial, to add Dr. John Siebert as an inventor and remove Dr. Partha Banerjee as a co-inventor. (Dey's Case Status Report, August 8, 2005, P 3.) Dey has since argued that it had no way of knowing the identity of the *842 patent*'s inventors "until after discovery was over and all of the sworn testimony of the many people involved in the development could be properly considered." (MFR, p. 16.)

In an Order dated November 4, 2005, the Court granted Eon's motion to shorten the 30-month stay. (Court's Order, Nov. 4. 2005.) The Court based its holding [*12] on a finding that Dey's failure to form a clear position on inventorship at the beginning of this action,

as reflected by its repeated changes of position on the issue, was unreasonable and would likely delay the action. (*Id.*) The Court further held that Dey had shown no legitimate basis for its delay in disclosing the 2003 study and producing documents pertaining to it. (*Id.*) Dey now seeks reconsideration of the Court's decision pursuant to *Federal Rule of Civil Procedure 60*.

B. Standard on a Motion for Reconsideration

Federal Rule of Civil Procedure 60(b) provides, "the court may relieve a party . . . from a final judgment, order, or proceeding for . . . (2) newly discovered evidence which by due diligence could not have been discovered in time to move for a new trial under *Rule 59(b)*; [or] (6) any other reason justifying relief from the operation of the judgment." *Fed. R. Civ. P. 60(b)*. A motion for reconsideration may be based on the availability of new evidence or the need to correct a clear error or prevent manifest injustice. *School Dist. No. 1J v. AC&S, Inc., 5 F.3d 1255, 1262 (9th Cir. 1993)*. [*13] Local *Rule 7-18* provides that a motion for reconsideration of a court's decision on a motion "may be made only on the grounds of "(a) a material difference in fact or law from that presented to the Court . . . that in the exercise of reasonable diligence could not have been known to the party moving for reconsideration at the time of [the Court's previous] decision, or (b) the emergence of new material facts or a change of law occurring after the time of such decision, or (c) a manifest showing of a failure to consider material facts presented to the Court before such decision." *L.R. 7-18*.

C. Dey's Motion for Reconsideration

Dey argues that reconsideration is warranted because "(a) material facts were not considered or were overlooked by the Court in forming its decision; (b) the November 4th Order incorrectly applie[d] the law of inventorship and the facts of this case; and (c) facts which became available after the hearing further demonstrate the failure to timely produce the 2003 study was unimportant and did not draw out discovery." (MFR, p. 5.) The Court will address each of these arguments in turn.

1. Failure to Consider Material Facts

Dey's first [*14] argument is that the Court's decision failed to consider certain facts material to the question whether Dey failed reasonably to cooperate in expediting this action. This argument relies on alleged errors in the Court's discussion of (1) Dey's changing position on inventorship, and (2) Dey's delay in disclosing the 2003 study and producing documents pertaining to it.

a. Inventorship

Dey takes issue with the Court's discussion of inventorship on several grounds. First, Dey argues that the Court based its ruling on a "wrong impression that there were only a few people who worked on the [development of the material in the *842 patent*] over a short period of time . . . [but that] there were in fact many people involved in the development process leading to the claimed invention and the development occurred over a period of about 8 years." (MFR p. 8.) Dey further argues that the Court's decision incorrectly "presupposes that (a) correction of inventorship can only occur with respect to a few inventors, among many and (b) Dey had sufficient facts in its possession from which it concluded that inventorship was wrong and that it believed Dr. Siebert was an inventor and Dr. Banerjee [*15] was not prior to the close of discovery." (MFR, pp. 9-10.)

Dey mischaracterizes the Court's decision. The Court's finding that Dey unreasonably failed to take a clear position on inventorship was not based on a perception that only a few individuals were involved in the process leading to the invention of the *842 patent*'s subject matter, or that Dey necessarily decided to correct inventorship before discovery closed. Nor was the decision based on a legal conclusion that inventorship can only be corrected as to a few inventors. The problem the Court identified with Dey's conduct was that Dey apparently made an insufficient effort to determine the true identity of the patented subject matter's inventors before initiating this litigation. Throughout this case Dey has denied that it has any obligation to investigate or acquire an informed opinion as to who the inventors are of the method claimed in the *842 patent*, such as through witness interviews or examination of its own internal records. Not only does Dey contend that it was entitled to wait until after the close of discovery to identify the inventors, but it also claims it is entitled to wait to do so until after the close of the [*16] evidence at trial. (Dey's Case Status Report, August 8, 2005, P 3.)

Dey's position is unreasonable. There is no reason Dey could not have conducted an investigation into the inventors' identity or formed a good faith opinion on the issue before it filed its Complaint. By Dey's own admission, its employees had been attempting to obtain FDA approval of the inhalation solution that was a precursor to DuoNeb since the early 1990s. Presumably Dey has documents indicating who was involved in the project's development and/or the process of seeking FDA approval during that time. Nor does Dey explain why it did not have a clearer position on inventorship before it filed the applications leading to the *842 patent*. Dey fails to explain its inability to identify the individuals most centrally involved in the conception of the claimed subject matter at any time prior to trial. For Dey to wait until the close of evidence at trial to assert its "true" position on

inventorship will likely raise a host of new disputed issues and prolong this action -- a result that could have been avoided by an adequate profiling inquiry.

Dey argues that it could not discover the patented material's inventors before [*17] the close of discovery because many of the people involved in the development process leading to the *842 patent* no longer worked for Dey as of the start of this litigation. (MFR, p. 16.) Dey further argues that, due to those possible contributors' "potential self-interest," Dey could not determine inventorship before receiving "sworn testimony" from them. (*Id.*) This argument, however, does not excuse Dey's failure to conduct a diligent investigation and make a reasonable determination on the issue of inventorship. Potential inventors' self-interest notwithstanding, there is no reason Dey could not have contacted and interviewed the people involved in the patented material's development process before bringing this action. Dey's concern regarding "self interest" could be addressed by investigating the bases of interviewees' statements and seeking corroboration from internal documents or from other former employees involved in the inhalation solution's development. Finally, Dey's assertion that it is entitled to postpone taking a position on inventorship until the close of evidence at trial is illogical even under its own reasoning: Even if Dey did need to obtain "sworn testimony" [*18] in discovery to determine the identity of the patented material's inventors, there appears to be no basis for Plaintiff's position that, having obtained such testimony, it still needed to wait until after the close of the evidence at trial.

Dey further argues that its changes of position on inventorship were not prejudicial to Eon because (1) Eon never propounded discovery to Dey asking Dey to identify the inventors, and (2) Dey made all information regarding conception of the patented material available to Eon by making Dr. Siebert available for a deposition and identifying all the people involved in the development process for DuoNeb. (MFR, p. 13.) These arguments are unpersuasive. First, the most likely reason Eon never asked Dey to identify the inventors of the material in the *842 patent* is that the patent itself already listed two named inventors. Eon was entitled to assume that Dey had named those two individuals for good reason, and that Dey had a factual basis for doing so. Second, the fact that Dey identified all of the people involved in the development of DuoNeb during discovery does not mean that Eon would not likely have asked those individuals different questions had [*19] it known that Dey regarded them as potential or actual inventors. (Eon's Motion to Shorten Stay, p. 7; Reply in Support of Motion to Shorten Stay, p. 6.)

Moreover, this case's history shows that Dey's failure to inform itself as to the identity of the *842 patent*'s inventors created problems in discovery. In March, 2005, Eon complained to Dey that the witness Dey had designated as its 30(b)(6) expert on the issue of inventorship and one of the people listed as an inventor on the *842 patent*, Dr. Imtiaz Chaudry, did not even work for Dey during the time Dey was developing DuoNeb, and had no knowledge as to who had been involved in its initial development. (Eon's Supplemental Reply Brief in Support of Motion to Shorten Statutory 30-Month Stay, Exh. H thereto.) Dey refused to designate any other 30(b)(6) witness, let alone anyone employed during DuoNeb's development, and stated that all individuals who were "still employed by Dey [who were involved in the development of DuoNeb] have been made available to you," and that Eon was "free to depose anyone you choose." (*Id.*). Dey also reiterated its position that "inventorship of the *842 patent* is presumptively correct as a matter of [*20] law." (*Id.*). Dey's position appears to have been that it had no obligation to designate any additional 30(b)(6) witness with information regarding the initial development process, or to make sure that Dr. Chaudry was informed about individuals involved in DuoNeb's development.

That is not the law. An entity designating a 30(b)(6) witness to testify on its behalf has an obligation to "make a conscious good faith endeavor to designate the persons having knowledge of the matters sought by [the interrogator] and to prepare those persons in order that they can answer fully [and] completely . . . the questions posed by [the interrogator] as to the relevant subject matters." *Protective National Insurance Co. of Omaha v. Commonwealth Insurance Co., 137 F.R.D. 267, 278 (D. Neb. 1989)* (*quoting Mitsui & Co. v. Puerto Rico Water Resources Authority, 93 F.R.D. 62, 67 (D.P.R. 1981)*). This duty to prepare witnesses extends not only to matters *actually* known by the designating party, but also to matters that "should be reasonably known" by it. *Alexander v. F.B.I., 186 F.R.D. 148, 152 (D.D.C. 1999)*. If it becomes clear that a designated [*21] deponent is unable to respond to relevant areas of inquiry specified by the inquiring party with reasonable specificity, the responding party must designate an additional 30(b)(6) witness. *Id. at 151*. Certainly, it is "reasonable" to expect that Dey would know the roles played by various of its own employees in the development of the inhalation solution described in the *842 patent*. Thus, if Dr. Chaudry was unable to provide information regarding who was involved in the development of DuoNeb in the years before he began working for Dey, Dey was obligated either to prepare him to provide such information or designate an additional 30(b)(6) witness. Its refusal to do either was unreasonable.

Finally, Dey argues that Eon is the one that has refused to cooperate in discovery. Dey argues that when it

propounded discovery to Eon in June, 2005, asking Eon to identify who *Eon* believed were the patented material's true inventors and the factual basis supporting that belief, Eon asserted "a host of objections, including attorney-client privilege and the work product doctrine, and made no attempt to identify any person it believed to be an inventor." (MFR, p. 17.) This argument [*22] also is unavailing. Dey's "unreasonable delay" in this case is not merely a failure to reveal facts in discovery but a failure to commence this litigation with an adequately-formed idea as to the identity of the *842 patent*'s inventors. While Eon might have been more forthcoming in response to Dey's discovery request, Eon is not the party that initiated this action. Dey, by filing suit before understanding the factual basis for its own position on inventorship, has created confusion and the potential for delay of the trial. n6

> n6 Dey also takes issue with this Court's statement that, "Dey's failure to have a clearer understanding on the identity of the actual inventors of the subject matter claimed in the *842 patent* . . . raises questions regarding its ownership rights under that patent." (MFR, p. 7; Nov. 4 Order, p. 4.) Dey argues that the Court should not have considered ownership because ownership is not in issue in this case. While Dey is correct that ownership per se is not in issue, in the sense that no person claiming to have been omitted as an inventor on the *842 patent* has made any claim of ownership in this case, the identity of the inventors under the *842 patent* could well bear on the fundamental question whether Dey has any rights under that patent. This is because "[i]nventorship provides the starting point for determining ownership of patent rights." 8 DONALD S. CHISUM, *CHISUM ON PATENTS § 22.02* (2005) (*citing University Patents Inc. v. Kligman, 762 F. Supp. 1212, 1218-19 (E.D. Pa. 1991)*). "[A]bsent some effective transfer or other obligation to assign patent rights, the individual inventor owns the right to apply for and obtain a patent." *Id.* Dey also argues that ownership is not in issue because "each [person who might claim to have been omitted as an inventor on the *842 patent*] is obligated to assign his rights, if any, to Dey." (MFR, p. 7.) However, this is far from a foregone conclusion. Absent some exception based on contract or the nature of one's employment, an employee owns patent rights in the subject matter of which he or she is the sole or joint inventor despite having conceived the invention or reduced it to practice in the course of her employment. 8 *CHISUM, § 22.03*; *Banks v. Unisys Corp., 228 F.3d 1357, 1359, 56 U.S.P.Q. 2d 1222, 1224 (Fed. Cir. 2000)*. Two exceptions to this rule are where the inventing employee is party to a contract giving the employer ownership rights in the invention, or where the employee was hired to invent something or solve a particular problem. *Banks, 228 F.3d at 1359, 56 U.S.P.Q. 2d at 1224*. Dey provides no evidence or argument indicating that either exception applies in this case, or substantiating its claim that all potential inventors under the *842 patent* would be obligated to assign their rights to it.

[*23]

b. Delayed Production of 2003 Study

Dey also challenges the Court's finding that Dey acted unreasonably in failing timely to disclose in discovery a study (the "DART Study") that it conducted in 2003 comparing DuoNeb to a drug known as Combivent MDI, and waited until after fact discovery had closed to produce documents pertaining to the study. Specifically, Dey takes issue with this Court's statement that:

> Dey fails to provide any justification other than inadvertence for its failure to produce in discovery documents relating to a study it conducted in 2003 comparing DuoNeb to Combivent MDI, which Defendants characterize as prior art to the *842 patent* and on which they say they will rely to prove patent invalidity.

(November 4 Order, p. 6.) Dey asserts that the Order incorrectly "conclu[ded] that the DART study was prior art.'" (MFR, p. 5.) According to Dey, the DART study could not be prior art to the *842 patent*, because the study was published in 2003, "several years after the 2001 effective date of the patent." (*Id.*) Thus, Dey argues, "the DART study cannot be used to invalidate [Plaintiff's] patent." (*Id.*)

Dey clearly does not understand [*24] the Court's reasoning on this issue. First, the Court's use of the term "prior art" did not refer to the DART study itself but to Combivent MDI. Second, the Court did not express any opinion as to whether Combivent MDI actually *was* "prior art" to the *842 patent*, but merely pointed out that *Eon* has taken the position in this action that it was. Indeed, Eon contends that Boehringer-Ingelheim's ("BI's") marketing of Combivent prior to Dey's obtaining the *842 patent* renders the *842 patent* invalid. Eon stated in its moving papers:

> One of the items which is prior art to the *842 patent*, and on which defendants will rely to prove invalidity of that patent, is a combination albuterol/ipratropium bromide product made and sold by Boehringer-Ingelheim, a competitor of [Dey's], under the name Combivent. n7

(Eon's Memorandum of Points and Authorities in Support of Motion to Shorten the 30-Month Statutory Stay, pp. 4-5.) The Court thus did not err when it pointed out that Eon characterizes *Combivent MDI* as invalidating prior art. Moreover, as Eon contends that BI was marketing Combivent MDI in 1999 (and perhaps earlier), and Dey contends that the *842 patent*'s effective [*25] date was December 28, 2001, n8 Dey's argument that the alleged prior art post-dated the *842 patent* is simply wrong.

> n7 Eon states that Combivent MDI is Combivent administered through a device known as a "multi dose inhaler." (Eon's Memorandum of Points and Authorities in Support of Motion to Shorten the 30-Month Statutory Stay, p.5.)

> n8 Plaintiff's MFR, p.5 n.6.

Dey cites *Glaxo, Inc. v. Torpharm, Inc., 1997 U.S. Dist. LEXIS 12816 (N.D. Ill., Aug. 28, 1997)* for the proposition that "a failure to timely produce documents where, as here, thousands of documents were produced, was held not to constitute a failure to expedite justifying shortening of the stay." (MFR, p.6.) *Glaxo* is inapposite. In *Glaxo*, the court held that the plaintiff did not fail to reasonably cooperate in expediting the litigation where it was still producing documents two months after the close of discovery, because "both parties [had] conducted a tremendous amount of discovery within a relatively short period [*26] of time," both parties had been forced to seek judicial intervention to resolve discovery disputes, some of the requesting party's discovery requests had been overbroad, and the plaintiff had otherwise cooperated in expediting the litigation. *Glaxo, 1997 U.S. Dist. LEXIS 12816, at *8-9*. The court did not say whether the late-produced documents were central to the claims in the case. In this case, by contrast, the late-produced study is central to Eon's contention that prior art invalidates the *842 patent*, Dey has given no explanation other than inadvertence for late disclosure of the study, and, as explained above, Dey has otherwise drawn out this case and created discovery disputes by commencing this litigation without a clear idea as to the inventors of the *842 patent*'s subject matter.

Dey further argues that Eon has not shown that Dey's delay in producing the 2003 study impeded the progress of this action. Dey argues that Eon did not take advantage of Dey's offer, upon producing the 2003 study, to provide Eon with additional discovery relating to the study at Dey's own expense. (MFR, p. 6.) Dey also argues that Eon has not propounded any discovery to Dey relating [*27] to the study in the four months since the DART study and related documents were produced. (MFR, p. 6.)

These arguments miss the point. First, the test under *21 U.S.C. § 355(j)(5)(B)(iii)* is whether a party "reasonably failed to cooperate in expediting" the litigation -- not whether it affirmatively delayed it. Moreover, fact discovery already had closed on all issues except those raised by Eon's newly-asserted counterclaims by the time Dey disclosed the DART study in July 2005. (2nd Amended Joint Stipulation Regarding Case Management Order.) Thus, that Eon has not propounded new discovery based on the DART study is not surprising.

2. Incorrect Application of Law

Dey further argues that the Court's decision incorrectly applied the law. First, Dey argues that the Court erred in failing to recognize that the law of inventorship is complex and that, as a result, Congress has allowed inventorship to be easily corrected under *35 U.S.C. § 256* as to any or all inventors listed on a patent. n9 Dey cites numerous cases for the proposition that inventorship is one of the most difficult and complex issues in patent law. (MFR, p. 10.) It also [*28] argues that inventorship is a question of law reviewed without deference by the Federal Circuit, that the inventors as named in an issued patent are presumed to be correct, and that a party seeking to be added to a patent as a co-inventor has the burden of proving by clear and convincing evidence that the inventor listed in the patent derived the invention from the claimant's work. (MFR, p. 10.) Although Dey does not explain how it believes these legal principles relate to its position that it did not fail reasonably to cooperate in expediting this action, Dey's argument presumably is that it should not be expected to have any position on inventorship prior to trial because inventorship is such a complex thicket.

> n9 *35 U.S.C. § 256* provides:
>
> Whenever through error a person is named in an issued patent as the inventor, or through error an in-

> ventor is not named in an issued patent and such error arose without any deceptive intention on his part, the Director may, on application of all the parties and assignees, with proof of the facts and such other requirements as may be imposed, issue a certificate correcting such error.
>
> The error of omitting inventors or naming persons who are not inventors shall not invalidate the patent in which such error occurred if it can be corrected as provided in this section. The court before which such matter is called in question may order correction of the patent on notice and hearing of all parties concerned and the Director shall issue a certificate accordingly.

[*29]

Without disputing Dey's characterization of the law on inventorship, the Court disagrees that those legal rules justify Dey's conduct in this case. Contrary to Dey's allegations, the only "law" that this Court applied in granting Eon's motion to lift the 30-month stay was the clause in *21 U.S.C. § 355(j)(5)(B)(iii)* allowing the Court to lift the stay where a party "fail[s] to reasonably cooperate in expediting the action." *21 U.S.C. § 355(j)(5)(B)(iii)*. That inventorship is a difficult legal issue does not excuse Dey's failure to conduct a thorough investigation, before suing for infringement, into the roles played by its various employees and former employees in the process culminating in the patented subject matter. Nor does the fact that inventorship is decided as a matter of law based on underlying facts. Dey's legal position on inventorship should have been informed by an adequate factual investigation from the start. Indeed, the fact that inventors as named in a patent are presumed to be correct cuts against Dey's argument that it is entitled to delay investigating the factual basis for its assertions of inventorship until after [*30] the close of the evidence at trial: That a patentee's assertion of inventorship is presumed correct presupposes that it is supported by a valid factual basis. That an opponent must produce clear and convincing evidence to overcome the presumption of correctness makes it all the more reasonable that the opponent should be informed prior to the close of discovery who the alleged inventors are as to whom it bears that evidentiary burden.

The legislative history of the Hatch-Waxman Amendments suggests that failure to conduct an adequate profiling investigation should come within *21 U.S.C. § 355(j)(5)(B)(iii)*'s scope. Those amendments were passed to smooth the "cumbersome drug approval process [which] delayed the entry of relatively inexpensive generic drugs into the market place." *In re Cardizem CD Antitrust Litigation, 105 F. Supp. 2d 618, 627 (E.D. Mich. 2000)* (*quoting Mylan Pharmaceuticals, Inc. v. Shalala, 81 F. Supp. 2d 30, 32 (D.D.C. 2000)*). The amendments reflect a Congressional intent "to make available more low cost generic drugs" and an effort "to balance two conflicting policy objectives: to induce name-brand pharmaceutical [*31] firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market." *Id.* (*quoting Mylan, 81 F. Supp. 2d at 32.*). n10 To permit a name-brand drug maker to derive hundreds of thousands of dollars each month from a patent, when it does not know who made the most significant contributions to the patented invention's conception, during an uninterrupted 30-month period following its filing suit on the patent, would frustrate Congress' intent to expedite the entry of less expensive drugs into the marketplace.

> n10 The Act's purpose of encouraging generic drug makers to market their products is demonstrated by the fact that the Act awards the first generic drug manufacturer to make a paragraph IV certification with an uninterrupted 180-day period free from competition from other generic competitors. That is, once the first generic manufacturer submits an ANDA, no other ANDA can be approved for the same generic product for 180 days, running from the date the prior ANDA applicant begins commercially marketing its drug. *Cardizem, 105 F. Supp. 2d at 628-29* (*quoting Mylan, 81 F. Supp. 2d at 33.*). *21 U.S.C. § 355 (j)(5)(B)(iv)* provides: "[I]f the [ANDA] contains a [subpart IV] certification, and is for a drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant." *21 U.S.C. § 355 (j)(5)(B)(iv)(I)*. "First applicant" is defined as "an applicant that, on the first day on which a substantially complete application containing a [subpart IV] certification . . . is submitted for approval of a drug, submits a substantially complete application that contains and lawfully maintains a certification described

in paragraph (2)(A)(vii)(IV) for the drug." *21 U.S.C. § 355(j)(5)(B)(iv)(II)(bb)*.

[*32]

Dey also argues that the Court's decision is mistaken because Dey's conduct in this case was "far less egregious than the patentee's conduct in *U.S. Indust., Inc. v. Norton Co.*, n11 where the corporate patent holder knew that there was a problem with inventorship, knew the name of the inventor more than a year before litigation commenced, and, despite failing to move for correction of inventorship until long after litigation commenced, still was not found to have delayed the case." (MFR, p. 18.) *Norton*, however, addressed significantly different circumstances from those present here. Most obviously, the issue in *Norton* was not whether to lift a statutory stay (indeed, the Hatch-Waxman Amendments creating the statutory stay had not even been passed at the time *Norton* was decided). Rather, the defendant patentee in *Norton* sought to correct inventorship by adding an inventor pursuant to *35 U.S.C. § 256*, and the plaintiff sought to prevent amendment on the grounds of laches. (*Id. at *1-2, 8-9.*) The court held that any prejudice from the patentee's delay in moving to amend inventorship would be more appropriately addressed by allowing for [*33] additional discovery than by "summary invalidation of the patent." *Id. at *11.*

n11 No. 71-CV-359, *1974 U.S. Dist. LEXIS 6377, 184 U.S.P.Q. (BNA) 187 (N.D.N.Y. Nov. 7, 1974)* (as amended).

Unlike in *Norton*, no party in this case seeks "summary invalidation" of the *842 patent*. Indeed, no party even argues that Dey should not be permitted to amend inventorship pursuant to *35 U.S.C. § 256*. Eon only seeks to terminate the statutory stay on FDA approval of its generic drug on the ground that Dey's failure to enter this litigation with a clear picture on inventorship has constituted a failure to reasonably cooperate in expediting the action. There is nothing inconsistent about holding both (1) that Dey may seek to correct inventorship if new facts demonstrate a need to do so, and also (2) that Dey nevertheless should be required to inform itself of the facts underlying its claims of inventorship early in the action rather than waiting until the close of the evidence at trial [*34] to discover the role played by each of its own current and former employees in the development of the patented material. Had the Hatch-Waxman Amendments been in effect at the time *Norton* was decided, and had the plaintiff sought to have the stay lifted, the *Norton* court might well have reached the same result that this Court reached in its decision.

Finally, Dey asserts that the Court's decision improperly penalizes Dey for engaging in a "non-frivolous assertion of its legal rights" to petition the Court and the PTO to correct inventorship pursuant to *35 U.S.C. § 256*. (MFR, p. 20.) It cites *Zeneca Ltd. v. Pharmachemie B.V., 16 F. Supp. 2d 112 (D. Mass. 1998)* for the proposition that *21 U.S.C. § 355(j)(5)(B)(iii)*'s standard of "fail[ing] to reasonably cooperate in expediting the action" is "not be construed so as to encompass nonfrivolous assertions of legal rights." (MFR, p. 20.) *Zeneca*, however, did not involve a party's failure to enter the case with an informed position on a key issue. Rather, the defendant in that case was alleged to have "failed reasonably to cooperate in expediting the action" by filing [*35] a motion (which ultimately was successful) contesting the court's exercise of personal jurisdiction over it. *Zeneca, 16 F. Supp. 2d at 116*. The court held that the defendant had a due process right not to be sued in a court that had no personal jurisdiction over it, that its motion had legal and factual support, and, thus, that the challenge to personal jurisdiction did not constitute unreasonable failure to cooperate in expediting the litigation. *Id.* In this case, by contrast, the challenged conduct is not Dey's exercise of its right to seek correction of inventorship under *35 U.S.C. § 256* per se, nor is it the filing of any motion with solid legal and factual support. This Court does not dispute that Dey has the right to correct inventorship under appropriate circumstances. The Court only takes issue with Dey's assertion that it did not have to make a good faith effort to identify the inventors of the subject matter claimed by the *842 patent* at the time it filed its application, before it initiated this litigation, and during the course of this litigation. n12

n12 Dey further argues that reconsideration is warranted based on facts that became available after the hearing on Eon's Motion to Shorten the 30-Month Stay. Specifically Dey argues that Eon's expert reports, produced after the hearing, did not rely on or refer to the DART study or documents associated with it. (MFR, p. 1.) However, Dey does not produce copies of those expert reports. Moreover, that Eon' experts may not have relied on or referred to the DART study does not decrease the high likelihood that Eon would not have conducted its discovery in a different way had the study been timely disclosed.

[*36]

D. Conclusion

For the foregoing reasons, Dey's motion for reconsideration of this Court's November 4, 2005 Order grant-

ing Eon's motion to shorten the statutory 30-month stay is DENIED.

DATED: December 22, 2005

CORMAC J. CARNEY

UNITED STATES DISTRICT JUDGE

EXHIBIT D

Westlaw.
Not Reported in F.Supp.2d
Not Reported in F.Supp.2d, 2000 WL 34213890 (D.N.J.)
(Cite as: Not Reported in F.Supp.2d)

H

Briefs and Other Related Documents

Warner Lambert Co. v. Purepac Pharmaceutical Co.D.N.J.,2000.Only the Westlaw citation is currently available.

United States District Court,D. New Jersey.

WARNER LAMBERT CO., Plaintiff,

v.

PUREPAC PHARMACEUTICAL CO. and Faulding Inc., Defendants.

PUREPAC PHARMACEUTICAL CO. and Faulding Inc., Plaintiffs,

v.

WARNER LAMBERT CO. and Godecke Aktiengesellschaft, Defendants.

No. Civ.A. 98-02749(JCL), Civ.A. 99-05948(JCL), Civ.A. 00-02053(JCL).

Dec. 22, 2000.

John J. Francis, Jr., Drinker, Biddle & Reath, Florham Park, NJ, for plaintiff.

Arnold B. Calmann, Saiber, Schlesinger, Satz & Goldstein, Esqs., Newark, NJ, for defendants.

OPINION

LIFLAND, J.

***1** Presently before the Court are the following three motions in cases involving Plaintiff Warner Lambert Co. ("Warner-Lambert") and Defendants Purepac Pharmaceutical Co. and Faulding Inc. (collectively referred to as "Purepac").

Docket No. 99-05948: Warner-Lambert moves, pursuant to Rule 12(b)(6), to dismiss Purepac's counterclaims alleging antitrust violations and unfair competition. That motion will be denied.

Docket No. 98-02749: Warner-Lambert moves for partial summary judgment dismissing Purepac's counterclaim alleging unfair competition, and in the alternative, Warner-Lambert moves to bifurcate the patent infringement claims from the unfair competition claims. That motion will be denied in part and granted in part.

Docket No. 00-02053: Warner-Lambert moves to dismiss Purepac's complaint which seeks a declaratory judgment of non-infringement. That motion will be granted.

BACKGROUND

A. First Lawsuit (98-2749):

The following facts are undisputed unless otherwise noted. Warner-Lambert discovered gabapentin in the mid-1970's. Warner-Lambert learned that gabapentin was useful in preventing and limiting epileptic seizures. In 1979, Warner-Lambert obtained U.S. Patent No. 4,087,544 (" '544 patent") covering the use of gabapentin to treat epilepsy. That patent expired on January 16, 2000.

On January 15, 1992, Warner-Lambert submitted a New Drug Application ("NDA") to the FDA for the use of gabapentin to treat epilepsy. On December 30, 1993, the FDA approved the NDA. According to the FDA's required labeling, gabapentin is useful for "adjunctive therapy in the treatment of partial seizures with and without secondary generalization in adults with epilepsy." The tradename used by Warner-Lambert for gabapentin is Neurontin.

In the late 1980's, Warner-Lambert discovered that gabapentin could be useful in slowing or preventing neurodegeneration. On January 28, 1992, Warner-Lambert received U.S. Patent No. 5,084,479 (" '479 patent") claiming the use of gabapentin to treat neurodegenerative diseases. That patent expires on January 2.2010. The '479 patent's dependent claims describe a method wherein the neurodegenerative disease is stroke, Alzheimer's disease, Huntington's disease, Amyotrophic Lateral Sclerosis (A.L.S.), and Parkinson's disease.

Before the late 1980's, gabapentin was known to exist in two principal forms: (1) an anhydrous form where no water is associated with the gabapentin molecules and (2) a hydrated form where some water is associated with the gabapentin molecules. Only two hydrated forms were known: (1) two gabapentin molecules associated with each molecule of water and (2) four gabapentin molecules associated with each

molecule of water.

In the late 1980's, two of Warner-Lambert's chemists discovered a new, previously-unknown form, where each gabapentin molecule is associated with one molecule of water. This monohydrate is very crystalline and could be purified to a high degree. After purification, the monohydrate can be readily converted back to the anhydrous form, containing no water. Warner-Lambert received U.S. Patent No. 4,894,476 (" '476 patent") on January 16, 1990 claiming the new monohydrate. The '476 patent expires on May 2, 2008.

***2** In early 1994, after receiving FDA approval for the use of gabapentin to treat epilepsy, Warner-Lambert began marketing gabapentin under the Neurontin label. Doctors also began to use Neurontin to treat neurodegenerative conditions such as Parkinson's disease, A.L.S. and neuropathic pain, even though it had not been approved by the FDA for such use. Increased awareness of these other uses of Neurontin led to significant sales for non-epilepsy uses. Today, more than 78% of Neurontin prescriptions are written for indications other than epilepsy, including the treatment of neuropathic pain and neurodegenerative diseases.

In the middle of 1997, Purepac began to look at the feasibility of selling a generic version of Neurontin. In conducting its feasibility studies, Purepac contacted two gabapentin suppliers. Plantex and Recon. Purepac settled on Plantex and the samples used to support its eventual application to the FDA were made with Plantex gabapentin.

On March 30, 1998, after completing work on its generic gabapentin. Purepac submitted its Abbreviated New Drug Application to the FDA. With this submission, Purepac was required to certify as to each patent covering gabapentin, which are listed in the "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"). The Orange Book contains all the patents that a pioneer manufacturer listed on its NDA to the FDA. As to Warner-Lambert's '544 patent (use of gabapentin to treat epilepsy). Purepac certified that it did not intend to market its generic gabapentin until that patent expired. Purepac also certified that Warner-Lambert's '476 gabapentin monohydrate patent would not be infringed by Purepac's manufacture and sale of generic gabapentin. Purepac did not certify as to Warner-Lambert's '479 patent (use of gabapentin to treat neuro-degenerative diseases). Alternatively, Purepac filed a statement of "inapplicable use."

After its certifications to the FDA. Purepac sent notice to Warner-Lambert. The Notice was received on June 1, 1998, and informed Warner-Lambert of Purepac's position regarding the '476 monohydrate patent. On July 14, 1998, Warner-Lambert brought this action alleging infringement of the '476 and '479 patents.

Purepac moved for summary judgment. On August 25, 1999, this Court denied the motion due to unresolved discovery issues surrounding the '476 patent and due to genuine issues of material fact as to whether Purepac would knowingly and actively induce infringement of the '479 patent.

B. Second Lawsuit (99-5948):

Purepac filed a subsequent Abbreviated New Drug Application with the FDA for a generic version of gabapentin in tablet form as opposed to the capsule form involved in 98-2749. Thereafter, Purepac certified that Warner-Lambert's '476 gabapentin monohydrate patent would not be infringed by Purepac's manufacture and sale of generic gabapentin.. After receiving notice on November 8, 1999, Warner-Lambert brought this second action against Purepac, also alleging infringement of the '476 and '479 patents.

***3** Purepac filed counterclaims against Warner-Lambert alleging, in pertinent part, violation of the antitrust laws and unfair competition. The counterclaims allege the following facts: Warner-Lambert fraudulently listed the '476 and '479 patents in the NDA to the FDA for approval of gabapentin anhydrous, under the brand name Neurontin. By listing these patents in the NDA, Warner-Lambert forced the FDA to include the patents in the Orange Book. Any generic gabapentin manufacturer is prevented from applying for an ANDA without listing the patents contained in the Orange Book and giving notice to

the patent holder. Once the required notice is given, the pioneer manufacturer has immediate authorization to institute infringement litigation even though the ANDA claims that there is no infringement. According to Purepac, Warner-Lambert listed the '476 patent even though the gabapentin monohydrate covered by the '476 patent was not used at any point during the production of Neurontin. The counterclaim further alleges that Warner-Lambert should not have listed the '479 patent because the labeling authorization for Neurontin permits treatment only for illnesses related to epilepsy.

Purepac contends that subsequent to this Court's denial of summary judgement in 98-2749, the capsule litigation, discovery has revealed that Purepac's form of gabapentin does not contain gabapentin monohydrate, thereby negating any possible infringement of the '476 patent.

C. Litigation Surrounding Patent '482 (00-2053 and 00-2931):

On April 25, 2000, Warner-Lambert was issued Patent 6,054,482 (" '482 patent") for "Lactam-Free Amino Acids." This patent covers gabapentin formulas which are low in lactam impurities. Purepac alleges that Warner-Lambert threatened to sue Purepac for infringement of the '482 patent based on the earlier ANDA applications to market generic gabapentin capsules and tablets.

There is a factual dispute as to the actual point at which the '482 patent was listed in the FDA Orange Book. The record indicates that Warner-Lambert submitted the '482 patent information to the FDA on April 25, 2000 via telecopier. However, Purepac provides the Declaration of Arona Same stating that she was unable to find the '482 patent listed in the Orange Book until May 16, 2000. On April 28, 2000 Purepac filed suit in this court seeking a declaratory judgment of non-infringement and invalidity of the '482 patent. *Purepac v. Warner-Lambert,* No. 00-02053(JCL). After locating the '482 patent in the Orange Book, Purepac amended its ANDA applications for both gabapentin tablets and capsules to include Paragraph IV certifications that Purepac's products do not infringe upon the '482 patent. The record indicates that Warner-Lambert received official notice of the Paragraph IV certifications on June 14, 2000. On August 28, 2000 Warner-Lambert filed a motion in this court to dismiss Purepac's complaint for lack of subject matter jurisdiction under Rule 12(b)(1) and for failure to state a claim under Rule 12(b)(6).

***4** On July 15, 2000, Warner-Lambert filed a complaint against Purepac in this Court alleging infringement of the '482 patent. *Warner-Lambert v. Purepac,* No. 00-02931(JCL).

I. Warner-Lambert's Motion to Dismiss Purepac's Counterclaims of Antitrust Violations in Docket No. 99-05948.

STANDARD OF REVIEW

A. Motion to Dismiss under 12(b)(6):

In deciding a motion to dismiss a counterclaim under Federal Rule of Civil Procedure 12(b)(6), all allegations in the counterclaim must be taken as true and viewed in the light most favorable to the counterclaimant. *See Warth v. Seldin,* 422 U.S. 490, 501, 95 S.Ct. 2197, 45 L.Ed.2d 343 (1975); *Trump Hotels & Casino Resorts, Inc., v. Mirage Resorts Inc. ,* 140 F.3d 478, 483 (3d Cir.1998); *Robb v. Philadelphia,* 733 F.2d 286, 290 (3d Cir.1984). A court may consider only the counterclaim, exhibits attached to the counterclaim, matters of public record, and undisputedly authentic documents if the counterclaims are based upon those documents. *See Pension Benefit Guar. Corp. v. White Consol., Indus.,* 998 F.2d 1192, 1196 (3d Cir.1993). If, after viewing the allegations in the light most favorable to the counterclaimant, it appears beyond doubt that no relief could be granted "under any set of facts which could prove consistent with the allegations," a court shall dismiss a counterclaim for failure to state a claim. *Hishon v. King & Spalding,* 467 U.S. 69, 73, 104 S.Ct. 2229, 81 L.Ed.2d 59 (1984); *Zynn v. O'Donnell,* 688 F.2d 940, 941 (3d Cir.1982).

Furthermore, "[I]n antitrust cases, where 'the proof is largely in the hands of the alleged conspirators.' dismissals prior to giving the plaintiff ample opportunity

for discovery should be granted very sparingly." *Hospital Building Co. v. Trustees of Rex Hospital*, 425 U.S. 738, 746, 96 S.Ct. 1848, 48 L.Ed.2d 338 (1976) (quoting *Poller v. Colombia Broadcasting*, 368 U.S. 464, 473, 82 S.Ct. 486, 7 L.Ed.2d 458 (1962)). "The liberal approach to the consideration of antitrust complaints is important because inherent in such an action is the fact that all details and specific facts relied upon cannot properly be set forth as part of the pleadings." *See Lucas Indus. v. Kendiesel, Inc.*, 1995 WL 350050, at *2 (D.N.J. June 9, 1995). This court must take "mere conclusions of the pleader" into account when deciding whether a claim for relief is stated. *See id.* at *2 (quoting *United States v. Employing Plasterers' Assn.*, 347 U.S. 186, 188 (1954)).

However, courts have determined that "the heavy costs of modern federal litigation, especially antitrust litigation, and the mounting caseload pressure on the federal courts," militate in favor of requiring some reasonable particularity in pleading violations of the federal antitrust laws." *See Sutliff, Inc. v. Donovan Co.*, 727 F.2d 648, 654 (7th Cir.1984); *Garshman v. Universal Resources Holding, Inc.*, 641 F.Supp. 1359, 1367 (D.N.J.1986).

DISCUSSION

Warner-Lambert argues that Purepac's counterclaims of antitrust violation should be dismissed for failure to state a claim because Warner-Lambert's claims of patent infringement are protected under the *Noerr-Pennington* doctrine. Furthermore, Warner-Lambert argues that Purepac lacks standing to bring a claim for antitrust injury.

A. Immunity under Noerr-Pennington Doctrine

1. Sham Litigation

***5** Purepac claims that Warner-Lambert initiated patent infringement litigation for the sole purpose of forestalling Purepac's ability to enter the gabapentin market. Warner-Lambert claims protection under the *Noerr-Pennington* doctrine of immunity for activities petitioning the government, including access to the courts for redress of grievances. *See Eastern R.R. President Conference v. Noerr Motor Freight*, 365 U.S. 127, 81 S.Ct. 523, 5 L.Ed.2d 464 (1961). Under this doctrine, Warner-Lambert would be immune from antitrust liability for the anti-competitive effects of its patent infringement litigation. *See Professional Real Estate Investors, et. al. v. Columbia Pictures Indus., Inc., et. al.*, 508 U.S. 49, 60, 113 S.Ct. 1920, 123 L.Ed.2d 611 (1993). However, there is an exception to this immunity when the patent infringement case is considered "sham" litigation, i.e. instituted for the sole purpose of precluding competition.

The Supreme Court has established the following test for "sham" litigation:
First, the lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits. If an objective litigant could conclude that the suit is reasonably calculated to elicit a favorable outcome, the suit is immunized under *Noerr*, and an antitrust claim premised on the sham exception must fail. Only if challenged litigation is objectively meritless may a court examine the litigant's subjective motivation. Under this second part of our definition of sham, the court should focus on whether the baseless lawsuit conceals 'an attempt to interfere directly with the business relationships of a competitor.'

Id. at 60-61 (quoting *Noerr*, 365 U.S. at 144).

Warner-Lambert argues that, as a matter of law, a patent infringement suit which survives summary judgment cannot be considered "objectively baseless" within the meaning of the "sham" litigation test. Warner-Lambert relies on *Harris Custom Builders, Inc. v. Hoffmeyer*, 834 F.Supp. 246, 261-62 (N.D.Ill.1993), which held that "[a]n action that is well grounded, factually and legally, to survive a summary judgment is sufficiently meritorious to lead a reasonable litigant to conclude that they had some chance of success on the merits." *Id. Harris Custom Builders* dealt with a case in which summary judgment of non-infringement was denied.

In this case, Warner-Lambert's claims survived summary judgment in the 98-2749 patent infringement action based on Purepac's application for generic gabapentin capsules. Purepac's antitrust counterclaims in 99-5984 are based on the capsule litigation in 98-2749, in combination with the infringement lit-

igation (99-5948) brought by Warner-Lambert after Purepac's application to market generic gabapentin tablets. Therefore, the denial of summary judgment in 98-2749 does not necessarily relate to the asserted basis for antitrust relief.

Moreover, denial of summary judgment denial, in and of itself, cannot deem litigation objectively reasonable without specific examination of the basis for denial of summary judgment. *See* Filmtech Corp. v. Hydranautics, 67 F.3d 931, 938 (Fed.Cir.1995) (citing *Boulware v. Nevada Dep't of Human Resources*, 960 F.2d 793, 798-99 (9th Cir.1992) ("a preliminary success on the merits does not preclude a court from concluding that litigation was baseless"). This Court's August 25, 1999 order denying summary judgment was based in part on unresolved discovery issues involving the '476 patent infringement claim. Consequently, the order, by itself, does not require a finding that Warner-Lambert's 98-2749 litigation was reasonably calculated to elicit a favorable outcome.

***6** As to the '479 patent infringement claim, this Court found that there was sufficient evidence to "create a genuine issue of material fact as to whether Purepac will knowingly and actively induce infringement of Patent '479." The '479 patent claims the use of gabapentin for treatment of neuro-degenerative diseases. However, the record indicates that this is an "off-label" use for Neurontin because the FDA has not approved Neurontin for treatment of neuro-degenerative diseases. Purepac's ANDA for a generic form of gabapentin only claims the method of use for treatment of epilepsy. Consequently, Purepac alleges that Warner-Lambert's claim of '479 patent infringement is merely a "sham" to disguise the anti-competitive goal of preventing Purepac from receiving FDA approval of their ANDA. The mere fact that summary judgment was denied in the 98-2749 litigation does not, in and of itself, preclude Purepac's counterclaims of antitrust violations.

2. Fraudulent Conduct

Purepac further claims that Warner-Lambert does not enjoy *Noerr-Pennington* immunity because Warner-Lambert fraudulently listed Patents '476 and '479 in the Neurontin NDA, which automatically triggered the FDA listing of both patents in the Orange Book. According to Purepac, any generic gabapentin manufacturer is prevented from applying for an ANDA without listing the patents contained in the Orange Book and giving notice to the patent holder, thereby triggering infringement litigation. Under the Hatch-Waxman Act, once a pioneer manufacturer has filed an infringement claim, approval of the generic manufacturer's ANDA is stayed for a period prescribed in 21 U.S.C. 355(c)(3)(C). Purepac argues that Warner-Lambert's fraudulent listing of the '476 and '479 patents in the NDA precluded Purepac's ability to compete in the market.

A counterclaim alleging that a patent infringement plaintiff "obtained patent by knowingly and willfully misrepresenting the facts" will "be sufficient to strip [the plaintiff] of its exemption from the antitrust liability." *Walker Process Equip., Inc. v. Food Machinery and Chemical Corp.*, 382 U.S. 172, 177, 86 S.Ct. 347, 15 L.Ed.2d 247 (1965). Historically, while regional law has always been applied to antitrust litigation, the Federal Circuit has held that "whether conduct in procuring or enforcing a patent is sufficient to strip a patentee of its immunity from antitrust law is to be decided as a question of Federal Circuit Law." *Nobelpharma v. Implant Innovations*, 141 F.3d 1059, 1067-68 (Fed.Cir.1998).

Warner-Lambert first argues that Purepac incorrectly implicates the fraud exception to *Noerr* because Purepac did not sufficiently allege fraud in the counterclaim. Purepac did not explicitly mention the word "fraud." However, in *Nobelpharma* the Federal Circuit defined the fraud exception to *Noerr-Pennington* immunity as "a knowing, willful and intentional act, misrepresentation, or omission." *Nobelpharma*, 141 F.3d at 1070. Purepac alleges that "Warner Lambert caused the '476 patent to be listed in the Orange Book knowing that it does not cover gabapentin sold under the trade name Neurontin ... Warner-Lambert improperly caused the '476 patent to be listed in the Orange Book. Warner Lambert's motive and intent in causing the '476 patent to be listed in the Orange Book was to forestall competition in the market for Gabapentin." *See* Answer and Counterclaim. ¶ 63-64. Purepac makes the same assertions regarding the '479 patent. *See* Answer and Counterclaim, ¶ 66-67. Pure-

pac adequately alleges that Warner-Lambert knowingly made misrepresentations to the FDA with the specific intent to prevent competition.

*7 Warner-Lambert next argues that Purepac does not apply the current law. Warner-Lambert cites *Armstrong Surgical Center, Inc. v. Armstrong County Mem. Hosp.*, 185 F.3d 154, 162 (3rd Cir.1999). *cert. denied*, 530 U.S. 1261, 120 S.Ct. 2716, 147 L.Ed.2d 982 (U.S. June 26, 2000) for the proposition that "liability for injuries caused by state action is precluded even where the action did so by bribery, deceit or other wrongful conduct that may have affected the decision making process." Warner-Lambert argues that even if it was fraudulent in listing the '476 and '479 patents, it is protected from antitrust liability because the FDA, as a state actor, controls the Orange Book and requirements for ANDA applicants.

However, the *Armstrong* case does not apply to this matter. Although *Armstrong* involves a private party who deceived a state department, the department also conducted independent investigations and provided for two separate reviews of the decision. *See id.* at 163. This differs from a situation where the alleged deceit and fraudulent conduct is directed at a regulatory agency which does not conduct independent investigations. Consequently, the *Armstrong* court drew a distinction from a typical patent case:
The decision making process [in a typical patent situation] was an ex parte one in which the Patent Office was wholly dependent on the applicant for the facts. While the Patent Office can determine the prior act from its own records, it effectively and necessarily delegates to the applicant the factual determinations underlying the issuance of a patent. Accordingly, when the applicant has submitted false factual information, the state action is dependent on financially interested decision making.

Id. at 164.

In this case, Purepac contends that the FDA relies solely upon the NDA applicant's information when listing patents in the Orange Book. *See* Answer and Counterclaim ¶ 47. Therefore, the FDA would be forced to rely upon fraudulent misrepresentations by Warner-Lambert. Viewing the allegations in the counterclaim in the light most favorable to Purepac, discovery could demonstrate fraudulent conduct by Warner-Lambert, thereby removing immunity from antitrust liability.

B. Antitrust Standing

Warner-Lambert argues that Purepac's counterclaims for violations of the Sherman Act must be dismissed because Purepac does not have standing to assert antitrust injury. The United Supreme Court has listed the appropriate guidelines for determining whether antitrust standing exists. *See Associated Gen. Contractors v. California State Council of Carpenters*, 459 U.S. 519, 534-45, 103 S.Ct. 897, 74 L.Ed.2d 723 (1983). This Court must decide:
(1) whether there is a causal connection between an antitrust violation and harm to the plaintiff and the defendants intended to cause that harm;
(2) whether the nature of the plaintiff's alleged injury was of the type the antitrust laws were intended to forestall;
(3) the directness or indirectness of the asserted injury;
***8** (4) whether the claim rests on some abstract or speculative measure of harm; and
(5) the strong interest in keeping the scope of complex antitrust trials within judicially manageable limits, avoiding both duplicative recoveries and the complex apportionment of damages.

See Indium Corp. of America v. Semi-Alloys, Inc., 781 F.2d 879, 882 (Fed.Cir.1985) (quoting *Associated Gen. Contractors*, 459 U.S. at 434-45).

These general guidelines have been supplemented by caselaw which focuses on the direct issue in this matter. The specific rules under 21 U.S.C. § 355(j)(5)(B)(iii) ("Hatch-Waxman Act") require a thirty-month stay on FDA approval for a generic pharmaceutical manufacturer's ANDA when the ANDA product becomes involved in patent infringement litigation with the pioneer manufacturer. *See* 21 U.S.C. § 355(j)(5)(B)(iii). Because "the commencement of litigation automatically delay[s] FDA approval of the generics' proposed drugs." the patent infringement plaintiff has the power to forestall a generic manufacturer's ability to market a product. *See*

Bristol-Meyers v. Ben Venue Lab., 90 F.Supp.2d 540, 544 (D.N.J.2000). Therefore, the generic manufacturer's injury does not merely result from the "structure of a regulated industry," but from the decision of the pioneer manufacturer to bring suit. *See id.* at 545. Consequently, the Supreme Court's requirement for a special "causal connection" and "directness" of injury must be liberally construed when dealing with regulatory conditions under the Hatch-Waxman Act.

In this case. Warner-Lambert instituted the patent infringement cases against Purepac. thereby delaying FDA approval of a generic form of gabapentin in either tablet or capsule form. This decision to delay approval of the ANDA was not left to the discretion of the FDA, so it cannot be attributed to the structure of the regulated industry. Warner-Lambert has exercised its power under Hatch-Waxman to temporarily foreclose Purepac's access to the market for gabapentin. Purepac has alleged a sufficient causal connection between Warner-Lambert's allegedly fraudulent conduct and Purepac's injuries.

Accordingly, this Court finds that Purepac has standing to bring antitrust counterclaims against Warner-Lambert.

II. Warner-Lambert's Motion for Partial Summary Judgment Against Purepac's Unfair Competition Counterclaim, or in the Alternative, Bifurcation of the Patent and Antitrust Claims in Docket No. 98-02749.

STANDARD OF REVIEW

Summary judgment eliminates unfounded claims without recourse to a costly and lengthy trial. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 327, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986). However, a court should grant summary judgment only "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." *Fed.R.Civ.P.* 56(c). The burden of showing that no genuine issue of material fact exists rests initially on the moving party. *See Celotex*, 477 U.S. at 323. A litigant may discharge this burden by exposing "the absence of evidence to support the nonmoving party's case." *Id.* at 325. In evaluating a summary judgment motion, a court must view all evidence in the light most favorable to the nonmoving party. *See Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 587, 106 S.Ct. 1348, 89 L.Ed.2d 538 (1986); *Goodman v. Mead Johnson & Co.*, 534 F.2d 566, 573 (3d Cir.1976).

***9** Once the moving party has made a properly supported motion for summary judgment, the burden shifts to the nonmoving party to "set forth specific facts showing that there is a genuine issue for trial ." *Fed.R.Civ.P.* 56(e); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986). The substantive law determines which facts are material. *Id.* at 248. "Only disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment." *Id.* No issue for trial exists unless the nonmoving party can demonstrate sufficient evidence favoring it such that a reasonable jury could return a verdict in that party's favor. *See id.* at 249.

DISCUSSION

A. Partial Summary Judgment

Warner-Lambert moves for summary judgment dismissing Purepac's unfair competition counterclaim. Warner-Lambert makes three arguments in support of summary judgment: A) New Jersey unfair competition claims only encompass the illegal "passing off" of a competitor's product as one's own product. B) Warner-Lambert's patent infringement suits against Purepac are protected under the *Noerr-Pennington* immunity doctrine, and C) Purepac does not have standing to bring the unfair competition claims because Purepac has suffered no injury.

In Part I of this opinion, the Court addressed Warner-Lambert's arguments regarding immunity under *Noerr-Pennington* and Purepac's alleged lack of standing. Warner-Lambert's brief admits the identical nature of the arguments:
In light of the substantial overlap of issues relating to defendants' unfair competition counterclaim in this

action and their antitrust and unfair competition counterclaim in [99-5948: capsule litigation], the discussion in Sections B and C [dealing with *Noerr-Pennington* and standing], *infra,* and in Warner-Lambert's memorandum in support of its Fed.R.Civ.P. 12(b)(6) motion to dismiss defendants' antitrust and unfair competition counterclaims in [99-5948: capsule litigation] is *essentially the same.*

Warner-Lambert's Brief at p.12 n. 2. Therefore, this Court will only address Warner-Lambert's first argument which addresses the scope of the New Jersey unfair competition claim.

Warner-Lambert argues that the New Jersey law of unfair competition is limited to the "passing-off" of one's goods as those of a competitor and similar deceptive practices. However, caselaw demonstrates that the unfair competition claim is not as narrow as Warner-Lambert contends.

Warner-Lambert relies on a district court decision which states that "under New Jersey common law, unfair competition encompasses two separate torts: (1) passing off one's goods or services as those of another; and (2) unprivileged imitation." *See* *Eli Lilly & Co. v. Russel Corp.*, 23 F.Supp.2d 460, 494 (D.N.J.1998). Warner-Lambert argues that Purepac's allegations of unfair competition do not fit into either category because Purepac's allegations are based only on sham litigation and fraudulent submissions of patent information to the FDA.

***10** The Court is inclined to follow the cases relied upon by Purepac. *See* *Biovail Corp. Int'l v. Aktiengesellschaft,* 49 F.Supp.2d 750 (D.N.J.1999); *Duffy v. Charles Schwab & Co., Inc.*, 97 F.Supp.2d 592 (D.N.J.2000). In *Biovail,* Judge Barry denied the defendants' motion to dismiss plaintiff's claims of unfair competition under New Jersey law because the conduct alleged was "injurious and otherwise unfair, improper and wrongful" and "having found that the conduct alleged by [plaintiff] constitutes, at least on the pleadings, possible antitrust violations, it is fair to say that the conduct states a claim under the much broader common law tort of unfair competition." *Biovail,* 49 F.Supp.2d at 777. In *Duffy,* Judge Cooper emphasized that although the defendant argued that the *Eli Lilly* case stood for the proposition that "only two types of claims may be brought under New Jersey's unfair competition law: (1) passing off, and (2) unprivileged imitation .... [t]he language of *SK & F* and *Eli Lilly* should not be read to limit the reach of New Jersey's unfair competition law to these two torts alone." *Duffy,* 97 F.Supp.2d at 601 n. 8. Accordingly, this Court rejects Warner-Lambert's argument that caselaw narrows the scope of unfair competition claims.

The Restatement (Third) of Unfair Competition suggests a broad range of unfair competition claims:
Certain recurring patterns of objectionable practices form the basis of the traditional categories of liability specifically enumerated in [the Restatement]. However, *these specific forms of unfair competition do not fully exhaust the scope of statutory or common law liability for unfair methods of competition* .... It is impossible to state a definitive test for determining which methods of competition will be deemed unfair in addition to those included in the categories of conduct described in the preceding Comments. Courts continue to evaluate competitive practices against generalized standards of fairness and social utility. *Judicial formulations have broadly appealed to principles of honesty and fair dealing, rules of fair play and good conscience, and the morality of the marketplace.* The case law, however, is far more circumscribed than such rhetoric might indicate, and courts have generally been reluctant to interfere in the competitive process. An act or practice is likely to be judged unfair only if it substantially interferes with the ability of others to compete on the merits of their products or otherwise conflicts with accepted principles of public policy recognized by statute or common law.

Restatement (Third) of Unfair Competition § 1 cmt. g (1995) (emphasis added). In fact, the comments to the Restatement state that unfair competition claims also apply to "one who interferes by instituting or threatening to institute groundless litigation against a competitor." *Id.* The Restatement explains that the somewhat narrow interpretation of unfair competition claims by caselaw is that "an act or practice is likely to be judged unfair only if it substantially interferes with the ability of others to compete on the merits of

their products."

***11** In this case, Purepac alleges Warner-Lambert's conduct has prevented the marketing of a generic form of gabapentin, thereby interfering with Purepac's ability to compete on the merits of the product described in its ANDA. The Court disagrees. Purepac's allegation of fraudulent submissions to the FDA falls within the scope of the unfair competition claims as defined by caselaw and the Restatement. Accordingly, this Court is unwilling to dismiss Purepac's counterclaims based solely on Warner-Lambert's narrow interpretation of New Jersey unfair competition law.

B. Bifurcation

As an alternative to dismissal, Warner-Lambert seeks the bifurcation of the patent claims from the unfair competition claims. Under the Federal Rules of Civil Procedure,

The court, in furtherance of convenience or to avoid prejudice, or when separate trials will be conducive to expedition and economy, may order a separate trial of any claim, cross-claim, counterclaim, or third-party claim, or of any separate issue or of any number of claims, cross-claims, counterclaims, third-party claims, or issues, always preserving inviolate the right of trial by jury as declared by the Seventh Amendment to the Constitution or as given by a statute of the United States.

Fed. R. Civ. P. 42(b). Generally, "[u]nder Rule 42(b), a district court has broad discretion in separating issues and claims for trial as part of its wide discretion in trial management." *Gardco Manufacturing, Inc. v. Herst Lighting Co.*, 820 F.2d 1209, 1212 (Fed.Cir.1987). The Federal Circuit has approved the "standard practice of separating for trial patent issues and those raised in an antitrust counterclaim." *In re Innotron Diagnostics*, 800 F.2d 1077, 1084 (Fed.Cir.1986); *see also Virginia Panel Corp. v. Mac Panel Co.*, 887 F.Supp. 880, 883-84 (W.D.Va.1995), *aff'd*, 133 F.3d 860 (Fed.Cir.1997); *Hunter Douglas Inc. v. Comfort Corp.*, 44 F.Supp.2d 145, 148 (N.D.N.Y.1999) (finding that the effort "to protect the property rights granted vis-a-vis the patent ... may be viewed as an attempt to extend them, temporally or otherwise, beyond the bounds set by the patent statute ... that allegedly runs afoul of the antitrust laws); *Alarm Device Mfg. Co. v. Alarm Products Intern., Inc.*, 60 F.R.D. 199, 202 (E.D.N.Y.1973) ("More often than not, separate trials of patent validity-infringement claims and misuse-antitrust claims have been found to be salutary"); *Brandt, Inc. v. Crane*, 97 F.R.D. 707, 708 (N.D.Ill.1983) (adopting the "general rule" that separating patent and antitrust issues serves the purposes of convenience, expedience, and economy).

The Federal Circuit has emphasized the necessity of bifurcation of antitrust claims and patent infringement claims because it "will enhance the parties' right to jury trial by making the issues the jury must consider less complex." *See Innotron*, 800 F.2d at 1086. When deciding a motion to bifurcate, the court should consider "whether one trial or separate trials will best serve the convenience of the parties and the court, avoid prejudice, and minimize expense and delay [and] the major consideration is directed toward the choice most likely to result in a just final disposition of the litigation." *Id.* at 1084.

***12** Purepac argues that bifurcation is inappropriate because "there will be substantial overlap between the issues relevant to the patent and unfair competition claims" based on allegations of Warner-Lambert's fraudulent statements to the FDA and sham litigation. This is probably true. However, caselaw indicates that such overlap supports bifurcation. *See Innotron*, 800 F.2d 1085 (holding that bifurcation was appropriate because defendant's affirmative defenses to the patent infringement case were identical to the antitrust counterclaims and therefore, "if [defendant] prevails at the trial on its affirmative defenses it need not again prove the same issues at the antitrust trial." In *Hunter*, the defendant in a patent infringement case brought antitrust counterclaims against the plaintiff alleging sham litigation. The court ordered bifurcation based on the following analysis:

if [plaintiff] succeeds in its patent infringement action, a significant portion of [defendant's] proof relative to its § 2 [Sherman Act] claim would become irrelevant. This could significantly shorten presentation of [defendant's] antitrust counterclaims. Likewise, during the patent infringement suit, [defendant]

would have an opportunity to present its defenses of patent invalidity and inequitable conduct. Resolution of these issues would become the law of the case and also eliminate some of the proof that would otherwise be necessary. Accordingly, the interest of judicial efficiency favors separating the patent issues from those grounded on antitrust principles.

Hunter, 44 F.Supp.2d at 152.

In this case, Purepac's antitrust claims based on sham litigation will be addressed during the patent infringement trial because the outcome of that trial may either support or eliminate Purepac's claim that Warner-Lambert filed an objectively baseless suit.

Purepac also contends that the unfair competition claim based on Warner-Lambert's allegedly fraudulent submission to the FDA, which caused an automatic stay of Purepac's ANDA approval, will be viable regardless of the outcome of the patent infringement trial. However, the patent infringement trial will resolve the scope of the '476 and '479 patents, which is relevant to a determination of whether Warner-Lambert could have engaged in inequitable conduct by listing the patents in the NDA for Neurontin.

Although Purepac relies on a few district court cases denying bifurcation, this Court finds that they are distinguishable. *See* *ACS Communications, Inc. v. Plantronics, Inc.*, 1995 WL 743726 (N.D.Cal. Dec.1, 1995) (denying bifurcation because the antitrust claim was filed before the patent infringement counterclaim); *General Tel. & Elec. Labs. Inc. v. National Video Corp.*, 297 F.Supp. 981 (N.D.Ill.1968) (denying bifurcation of all counterclaims in a patent infringement case involving counterclaims which alleged *both* antitrust violations *and* new patent infringement claims); *Spectra-Physics Lasers, Inc. v. Uniphase Corp.*, 144 F.R.D. 99 (N.D.Cal.1992) (denying bifurcation of issues of liability and damages).

***13** Therefore, this Court concludes that bifurcation would best serve the interests of justice.

III. Warner-Lambert's Motion to Dismiss Purepac's Complaint Seeking Declaratory Judgment of Non-Infringement under Rule 12(b)(1) and Rule 12(b)(6) in Docket No. 00-02053.

STANDARD OF REVIEW

A defendant may challenge the court's subject matter jurisdiction in two ways. First, defendant may attack the jurisdictional allegations of a complaint on its face. *See* *Cardio-Medical Ass'n Ltd. v. Crozer-Chester Med. Ctr.*, 721 F.2d 68, 75 (3d Cir.1983) (commenting that the Court in assessing a Rule 12(b)(1) motion based on [a facial jurisdictional attack] on the pleadings must assume that the allegations contained in the complaint are true and holding that allegations in complaint were sufficient to meet jurisdictional requirement of Sherman Act) (citations omitted). The second way to bring a 12(b)(1) motion is a factual jurisdictional attack, in which case the Court may rely on competent evidence other than the complaint. *See* *Land v. Dollar*, 330 U.S. 731, 735 n. 4, 67 S.Ct. 1009, 91 L.Ed. 1209 (1947) (noting that "when a question of the District Court's jurisdiction is raised, ... the court may inquire by affidavits or otherwise, into the facts as they exist").

Therefore, unlike a 12(b)(6) motion, in considering a 12(b)(1) motion based on a factual jurisdictional attack to a complaint, "no presumptive truthfulness attaches to plaintiff's allegations, and the existence of disputed material facts will not preclude the trial court from evaluating for itself the merits of jurisdictional claims. Moreover, [in defending against a factual jurisdictional attack], the plaintiff will have the burden of proof that jurisdiction does in fact exist." *Mortensen v. First Fed. Savings & Loan Ass'n*, 549 F.2d 884, 891 (3d Cir.1997) (vacating dismissal of Sherman Act claim for lack of subject matter jurisdiction and finding that "a combination of the timing of the factual jurisdictional attack, the plaintiff's having the burden of proof, and the court's having a free hand in evaluating jurisdictional evidence ... can unfairly preclude Sherman Act plaintiffs from reaching the merits of their cases"); *Lang v. Rubin*, 73 F.Supp.2d 448, 450 (D.N.J.1999). "That the district court is free to determine facts relevant to its jurisdiction has long been clear." *Mortensen*, 549 F.2d at 891 n. 16 (citing *Wetmore v. Rymer*, 169 U.S. 115, 18 S.Ct. 293, 42 L.Ed. 682 (1898)). "[D]ismissal for lack of subject matter jurisdiction is not appropriate

merely because the legal theory alleged is probably false, but only because the right claimed is 'so insubstantial, implausible, foreclosed by prior decisions of this Court, or otherwise completely devoid of merit as not to involve a federal controversy." ' *Growth Horizons, Inc. v. Delaware County, Pa.*, 983 F.2d 1277, 1280-81 (3d Cir.1993) (reversing dismissal for lack of subject matter jurisdiction on Fair Housing Act claim) (quotation omitted). "The threshold to withstand a motion to dismiss under Fed.R.Civ.P. 12(b)(1) is thus lower than that required to withstand a Rule 12(b)(6) motion." *Lunderstadt v. Colafella*, 885 F.2d 66, 70 (3d Cir.1989) (quotation omitted).

DISCUSSION

1. Rule 12(b)(1) Motion to Dismiss for Lack of Subject Matter Jurisdiction

***14** Warner-Lambert argues that Purepac has violated the Declaratory Judgment Act by filing the instant complaint as a mere pre-emptive strategy to avoid the statutory provisions of the Hatch-Waxman Act.

The Declaratory Judgment Act provides:
[i]n a case of actual controversy within its jurisdiction, except with respect to Federal taxes ..., any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought. Any such declaration shall have the force and effect of a final judgment or decree and shall be reviewed as such.

§ 28 U.S.C. 2201.

The Federal Circuit has set standards regarding jurisdiction of declaratory judgment claims against a patentee. *See Fina Research v. Baroid Ltd.*, 141 F.3d 1479, 1481 (Fed.Cir.1998); *Genentech, Inc. v. Eli Lilly & Co.*, 998 F.2d 931, 936-37 (Fed.Cir.1993). "We regularly review whether there is jurisdiction over an action seeking a declaratory judgment." *Fina*, 141 F.3d at 1481; *see generally Super Sack Mfg. Corp. v. Chase Packaging Corp.*, 57 F.3d 1054, 1058-59 (Fed.Cir.1995). In *Fina*, the Federal Circuit held:

[t]o determine whether there is an actual controversy in declaratory judgment actions involving allegations of patent non-infringement, invalidity, or unenforceability, we apply a two-prong inquiry: There must be both (1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory plaintiff that it will face an infringement suit, and (2) present activity which could constitute infringement or concrete steps taken with the intent to conduct such activity.

Fina, 141 F.3d at 1481 (citing *Super Sack*, 57 F.3d at 1058 (quoting *BP Chems. Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 978 (Fed.Cir.1993)). *See also Genentech*, 998 F.2d at 936-37. Although the court has discretion to decide whether subject matter jurisdiction exists, "the exercise of discretion in [deciding to entertain] a declaratory judgment must have a basis in sound reason" and conform to the established rule. *Genentech*, 998 F.2d at 936.

A. The Hatch-Waxman Act

The Hatch-Waxman Act was enacted to regulate the interplay between pioneer drug manufacturers and generic drug manufacturers. When filing an NDA, the pioneer applicant must file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted. *See* 21 U.S.C. 355(b)(1). Upon approval of the NDA, any claimed patents for the approved drug are published in the Orange Book. *See* 21 U.S.C. 355(j)(7)(A)(iii).

A generic manufacturer of the original drug approved by the NDA must file an ANDA with the FDA. The ANDA applicant must also certify as part of the application that for each patent listed: (I) such patent information has not been already filed; (II) such patent has expired; (III) the date on which such patent will expire; or (IV) such patent is invalid or will not be infringed by the manufacture, use, or sale of the generic drug. *See* 21 U.S.C. 355(j)(2)(A)(vii). An ANDA applicant making a Paragraph IV certification must provide notice to the owner of the patent and the

holder of the approved NDA for the listed drug, stating that it has submitted an ANDA and including a "detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." § 21 U.S.C. 355(j)(2)(B)(ii). Furthermore, a Paragraph IV certification creates a cause of action for patent infringement. If, within 45 days of receiving notice, the patent owner sues the ANDA applicant for patent infringement, the ANDA approval is essentially stayed for 30 months. *See* 21 U.S.C. 355(j)(5)(B)(iii).

***15** The statute also provides that during the 45-day period after the ANDA applicant gives notice of its Paragraph IV certification, "no action may be brought under section 2201 of Title 28 for a declaratory judgment with respect to the patent." § 21 U.S.C. 355(j)(5)(B)(iii)(III).

The legislative history of the Hatch-Waxman Act states that:
No action for a declaratory judgment regarding the patent at issue may be brought before the expiration of the 45 day period commencing with the provision of notice of the certification of patent invalidity or non-infringement. After the 45 day period, any suit for declaratory judgment regarding the patent at issue must be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

H.R. Rep. 98-857(I), 98th Cong., 2ND Sess.1984. at 47.

The purpose of the forty-five day period is to provide the patentee time in which to bring suit for patent infringement. Although the legislative history allows for a declaratory judgment action after the forty-five day period, there is no indication that Congress meant to permit the alleged infringer to bring a declaratory judgment action before the commencement of the forty-five day period.

Purepac contends that the forty-five day period during which a declaratory judgment action is prohibited did not commence until Purepac filed the Paragraph IV certification and notice. Because the FDA was late in filing the '482 patent in the "Orange Book." Purepac did not know whether it was necessary to file the Paragraph IV certification for two weeks. Before that two-week period expired, and before Purepac filed its Paragraph IV certification. Purepac brought suit for declaratory judgment against Warner-Lambert. This Court rejects Purepac's argument that its declaratory judgment action is permitted.

The record indicates that Warner-Lambert filed Patent '482 with the FDA (for purposes of listing in the Orange Book) immediately after receiving approval from the U.S. Patent Office on April 25, 2000. Purepac claims that the '482 patent was not listed in the Orange Book until May 16, 2000. However, any delay in the actual listing of patents in the Orange Book is not attributable to Warner-Lambert because the FDA controls the Orange Book. This Court is not in a position to modify the clear intent of the Hatch-Waxman Act because of delays attributable to the FDA's clerical system. 21 U.S.C. 355(j)(5)(B)(iii)(III) is meant to give the patentee a limited period of time to decide whether to bring suit for infringement before a declaratory judgment action can be instituted by a generic drug manufacturer.

In this case, Warner-Lambert was issued the '482 patent on April 25, 2000 and Warner-Lambert submitted the patent information to the FDA on that same day. Purepac became aware of the '482 patent and Purepac filed a declaratory judgment action on April 28, 2000. Purepac alleges that the action was properly filed because the '482 patent had not yet been listed in the Orange Book. Purepac did not amend their generic gabapentin ANDA until after May 16, 2000 and Warner-Lambert did not receive Purepac's Paragraph IV certification until June 14, 2000.

***16** After review of the Hatch-Waxman Act, this Court finds that Congress' dominant intent was to create a thirty-month period during which a pioneer manufacturer could be free from generic competition if it started suit to determine whether a generic manufacturer has infringed an existing patent. This period is triggered by the filing of infringement litigation by the pioneer manufacturer. The suit itself is triggered by the Paragraph IV certification and notice submitted by the generic manufacturer. Once a Paragraph IV certification is made, a suit seeking a declaratory

judgment of non-infringement and/or invalidity should be discontinued. Congress' secondary intent under the Hatch-Waxman Act was to establish a sequential series of events based on the assumption that the following would occur in this order: patent, NDA. ANDA and Paragraph IV certification. However, the facts in this case did not occur in the temporal sequence assumed by the Hatch-Waxman Act. In choosing which Congressional intent to enforce, this Court chooses the broader intent because the thirty-month moratorium is more critical to the Congressional scheme than the procedural sequence of events. The Court further notes that infringement litigation has already commenced on the '482 patent. Accordingly, the appropriate resolution is to dismiss the declaratory judgment action.

Caselaw offers minimal guidance as to whether generic drug companies can file declaratory judgment claims before the FDA lists the patent in the Orange Book. Both Purepac and Warner Lambert rely on different theories espoused in *Ben Venue Lab., Inc. v. Novartis Pharm. Corp.*, 10 F.Supp.2d 446, 451-52, (denying a motion to dismiss complaint for lack of subject matter jurisdiction). In *Ben-Venue,* the alleged infringing plaintiff filed a claim seeking a declaratory judgment that one of the defendant's patents was improperly listed in the Orange Book because the defendant deceived the FDA. Although this claim was filed during the forty-five day period set forth in the Hatch-Waxman Act, the court permitted the claim. The court reasoned that 21 U.S.C. 355(j)(5)(B)(iii)(III) "is limited to declaratory judgment actions ... aimed solely at the narrow patent issues of infringement and invalidity." *Id.* at 451.

In this case, Purepac seeks a declaratory judgment that Warner-Lambert's '482 patent is invalid and Purepac's generic form of gabapentin does not infringe. This is the exact type of claim that the Hatch-Waxman Act prohibits before the expiration of the forty-five day period.

The Federal Circuit has offered some guidance in the construction of the Hatch-Waxman Act in *DuPont Merck Pharm. Co. v. Bristol-Meyers Squibb Co.*, 894 F.Supp. 804 (D.Del.1995), *aff'd* 62 F.3d 1397 (Fed.Cir.1995). In *DuPont,* the Federal Circuit affirmed the lower court's dismissal of plaintiff's complaint seeking a declaratory judgment of patent invalidity and non-infringement. The plaintiff, a generic drug manufacturer, had not filed a Paragraph IV certification or given notice to defendant regarding patents which had an extended expiration date due to the Uruguay Round Agreement Acts ("URAA"). The lower court held that "an actual controversy for purposes of the Declaratory Judgment Act will only occur upon the filing of the appropriate paragraph IV certification by [plaintiff] with the FDA." *See Dupont,* 894 F.Supp. at 809. In affirming this decision, the Federal Circuit held that the special protections of the URAA did not insulate an alleged patent infringer from following the necessary steps under 21 U.S.C. 355(j)(5)(B)(iii)(III). *See id.*

***17** Similar to the *DuPont* court's reasoning, this Court is not prepared to let the filing methods of the FDA interfere with the purpose and intent of the Hatch-Waxman Act.

B. The First-Filed Rule

Purepac argues that this Court cannot dismiss its suit for declaratory judgment by application of the first-filed rule. The Court of Appeals for the Third Circuit has adopted the "first-filed rule" which applies to parallel cases filed in separate district courts. *See EEOC v. University of Pa.*, 850 F.2d 969, 971 (3d. Cir.1988); *Crosley Corp. v. Hazeltine Corp.*, 122 F.2d 925, 929 (3d Cir.1941), *cert. denied.* 315 U.S. 813, 62 S.Ct. 798, 86 L.Ed. 1211 (1942). "In all cases of federal concurrent jurisdiction, the court which first has possession of the subject must decide it." *Crosley Corp. v. Hazeltine Corp.*, 122 F.2d 925, 929 (3d Cir.1941) (quoting *Smith v. McIver*, 22 U.S. (9 Wheat.) 532, 6 L.Ed. 152 (1824)), *cert. denied,* 315 U.S. 813, 62 S.Ct. 798, 86 L.Ed. 1211 (1942). Consequently, trial judges may exercise their discretion to enjoin subsequent prosecution of "similar cases ... in different federal district courts." *EEOC,* 850 F.2d at 971.

Although the first-filed rule gives the trial court broad discretion. Third Circuit precedent has established certain exceptions to the application of the rule, including forum-shopping, bad faith, and in-

equitable conduct. *See* EEOC, 850 F.2d at 971. "We emphasize, however, that invocation of the rule will usually be the norm, not the exception. Courts must be presented with exceptional circumstances before exercising their discretion to depart from the first-filed rule." *Id.* at 979.

Purepac relies on *Genentech Inc. v. Eli Lilly & Co.*, 998 F.2d 931 (Fed.Cir.1993), where the court applied the first-filed rule to patent litigation and rejected the reasoning of *Tempco v. Electric Heater Corp. v. Omega Eng'g Inc.*, 819 F.2d 746 (7th Cir.1987) (holding that the first-filed rule does not apply to trademark cases). In applying the first-file rule to patent litigation, the *Genentech* court gave the following rationale:

[s]uch a rule [in *Tempco*] would automatically grant the patentee the choice of forum, whether the patentee had sought-or sought to avoid-judicial resolution of the controversy. This shift of relationship between litigants is contrary to the purpose of the Declaratory Judgment Act to enable a person caught in controversy to obtain resolution of the dispute, instead of being forced to await the initiative of the antagonist.... We prefer to apply in patent cases the general rule whereby the forum of the first-filed case is favored, unless considerations of judicial and litigant economy, and the just and effective disposition of disputes, require otherwise.

Id. at 937. In relation to patent cases, the first-filed rule is used only as protection against a patentee's ability to forum-shop. However, in this case the suit for declaratory judgment and the litigation of patent infringement claims are reciprocal cases which are both filed in this Court. Therefore, forum selection is not an issue.

***18** Moreover, the *Genentech* decision differs from the immediate case because the *Genentech* decision dealt with DNA technology which was not subject to FDA regulations. Therefore, in *Genentech,* there was no statutory regulation analogous to the Hatch-Waxman Act which prohibited suit. Accordingly, this Court finds that subject matter jurisdiction is lacking over Purepac's claim for a declaratory judgment.

2. Motion to Dismiss for Failure to State a Claim

Warner-Lambert seeks to dismiss Purepac's complaint for failure to state a claim. Because this Court holds that subject matter jurisdiction is lacking over Purepac's declaratory judgment complaint, due to the Hatch-Waxman Act. Warner Lambert's 12(b)(6) motion to dismiss the complaint need not be addressed.

I. Docket No. 99-05948

For the reasons set forth in the accompanying opinion IT IS on this *22nd* day of December, 2000 ORDERED that Warner Lambert's motion to dismiss Purepac's counterclaims three through five is denied.

II. Docket No. 98-02749

For the reasons set forth in the accompanying opinion IT IS on this *22nd* day of December, 2000 ORDERED that Warner Lambert's motion to dismiss Purepac's counterclaims alleging unfair competition is denied; and it is further

ORDERED that Warner Lambert's motion to bifurcate the patent infringement claims from the unfair competition counterclaims is granted.

III. Docket No. 00-02053

For the reasons set forth in the accompanying opinion IT IS on this *22nd* day of December, 2000 ORDERED that Warner Lambert's motion to dismiss Purepac's complaint seeking a declaratory judgment is granted.

D.N.J.,2000.
Warner Lambert Co. v. Purepac Pharmaceutical Co.
Not Reported in F.Supp.2d, 2000 WL 34213890 (D.N.J.)

Briefs and Other Related Documents (Back to top)

• 2:00CV02053 (Docket) (Apr. 28, 2000)

END OF DOCUMENT

EXHIBIT E

LEXSEE 2002 US DIST LEXIS 14914

FIRST GRAPHICS, INC., Plaintiff, vs. M.E.P. CAD, INC., Defendant.

Case No. 00 C 2524

UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS, EASTERN DIVISION

2002 U.S. Dist. LEXIS 14914

August 13, 2002, Decided
August 14, 2002, Docketed

PRIOR HISTORY: *First Graphics, Inc. v. M.E.P. Cad, Inc., 2002 U.S. Dist. LEXIS 4052* (N.D. Ill., Mar. 13, 2002)

DISPOSITION: [*1] M.E.P.'s Motion for Attorneys' Fees [item # 96-1] denied.

COUNSEL: For FIRST GRAPHICS, INC., plaintiff: Arne M. Olson, Joseph Ming Kuo, Olson & Hierl, Chicago, IL.

For M.E.P. CAD, INC., defendant: Lee F. Grossman, Janine Michelle Girzadas, Eric P Martin, Marshall, O'Toole, Gerstein, Murray & Borun, Chicago, IL.

For M.E.P. CAD, INC., defendant: Scott L. Terrell, P.C., Golden, CO.

For M.E.P. CAD, INC., counter-claimant: Lee F. Grossman, Janine Michelle Girzadas, Marshall, O'Toole, Gerstein, Murray & Borun, Chicago, IL.

For M.E.P. CAD, INC., counter-claimant: Scott L. Terrell, Scott L. Terrell, P.C., Golden, CO.

For FIRST GRAPHICS, INC., counter-defendant: Arne M. Olson, Joseph Ming Kuo, Olson & Hierl, Chicago, IL.

JUDGES: MATTHEW F. KENNELLY, United States District Judge.

OPINION BY: MATTHEW F. KENNELLY

OPINION:

MEMORANDUM OPINION AND ORDER

MATTHEW F. KENNELLY, District Judge:

First Graphics, Inc. sued M.E.P. Cad, Inc., contending that M.E.P.'s AutoSprink software infringed three of its patents. On March 13, 2002, the Court granted summary judgment in M.E.P.'s favor, finding that First Graphics' patents were not infringed. *See First Graphics, Inc. v. M.E.P. Cad,* [*2] *Inc.*, No. 00 C 2524, *2002 U.S. Dist. LEXIS 4052, 2002 WL 389535* (N.D. Ill., May 13, 2002). This case is now before the Court on M.E.P.'s motion for attorneys' fees pursuant to *35 U.S.C. § 285.*

Background

First Graphics is the owner of U.S. Patent Nos. 5,227,983, 5,557,537, and 5,808,905, which cover methods and apparatus for designing distribution systems for buildings (*e.g.,* plumbing, electrical, sprinkling, or ventilation systems) using computer software. M.E.P.'s AutoSprink software is a computer-aided design program for fire sprinkler systems. First Graphics sued M.E.P. claiming that AutoSprink, and more particularly the "3-point wizard" feature of AutoSprink, infringes its patents.

On March 13, 2002, the Court granted summary judgment of non-infringement in favor of M.E.P. As the Court concluded in the claim construction phase of this proceeding, the word "comply" in the First Graphics patents means "to act in accordance with standards or requirements." *First Graphics, Inc. v. M.E.P. Cad, Inc.,* No. 00 C 2524, *2001 U.S. Dist. LEXIS 10239, 2001 WL 755138,* at *6. M.E.P. argued on summary judgment that AutoSprink does not electronically design a layout "to comply" -- [*3] *i.e.,* act in accordance -- with the requirements of a building standard, a required claim element. *See, e.g.,* U.S. Patent No. 5,227,983, col. 18, ll. 17-23. The Court agreed, finding that AutoSprink does not automatically design a layout in accordance with building standards or requirements. Instead, it is the software user that produces a building-appropriate layout -- not

the program. The program itself makes no independent decisions to ensure compliance with building standards, but instead relies on inputs from the user. The Court accordingly entered a finding of non-infringement in favor of M.E.P. *See, e.g., Watts v. XL Systems, Inc., 232 F.3d 877, 884 (Fed. Cir. 2000)*(the absence of a single claim element or its equivalent precludes a finding of infringement).

On March 25, 2002, First Graphics filed a motion for reconsideration and requested that it be permitted to present an in-court demonstration of AutoSprink. The Court granted this request and viewed the demonstration on April 19, 2002. After reviewing the AutoSprink demonstration and the parties' written submissions, the Court denied First Graphics' motion for reconsideration.

Discussion [*4]

Under *35 U.S.C. § 285,* "the court in exceptional cases may award reasonable attorney fees to the prevailing party" in a patent infringement lawsuit. Conduct which may serve as the basis for an award of attorneys' fees includes "willful infringement, inequitable conduct before the [Patent Office], misconduct during litigation, vexatious or unjustified litigation, and frivolous suit." *Beckman Instruments, Inc. v. LKB Produkter AB, 892 F.2d 1547, 1551 (Fed. Cir. 1989).* An exceptional case pursuant to § 285 must be established by clear and convincing evidence. *Id.* In general, an attorneys fees award is appropriate only if "it would be grossly unjust that the winner be left to bear the burden of his own counsel which prevailing litigants normally bear." *Badalamenti v. Dunham's, Inc., 896 F.2d 1359, 1364 (Fed. Cir. 1990)*(quoting *J.P. Stevens Co. v. Lex Tex Ltd., 822 F.2d 1047, 1052 (Fed. Cir. 1987)).*

In support of its claim for attorneys' fees, M.E.P. argues that this case is "exceptional" within the meaning of *35 U.S.C. § 285* because First Graphics (1) instituted and prosecuted a lawsuit [*5] it knew was meritless; and (2) engaged in various instances of misconduct, including threatening the industry that purchasing AutoSprink would result in litigation; serving subpoenas on M.E.P.'s customers; and obtaining information from M.E.P. representatives while they were represented by counsel. For the following reasons, the Court concludes that M.E.P. has failed to demonstrate an exceptional case by clear and convincing evidence.

I. *Instituting and Prosecuting A Meritless Lawsuit*

In support of its argument that First Graphics instituted and prosecuted a meritless lawsuit, M.E.P. first argues that First Graphics failed to conduct a reasonable investigation prior to filing suit. According to M.E.P., if First Graphics had investigated its claim and obtained a copy of AutoSprink prior to filing suit, "it would have been immediately apparent that there was no infringement." M.E.P.'s Motion for Fees at 9. But First Graphics has provided evidence that it did in fact perform a pre-filing investigation of its case: it obtained and reviewed a demo-copy of AutoSprink and informational materials about the program, and it procured two opinion letters construing the patent claims [*6] and comparing those claims to the alleged infringing device. *See Antonious v. Spalding & Evenflo Companies, Inc., 275 F.3d 1066, 1073 (Fed. Cir. 2002)* (attorney who filed patent infringement action must compare the accused device with patent claims). It also provides evidence that M.E.P. refused to provide, until compelled to do so during discovery, a fully-functioning copy of AutoSprink. Based on this evidence, the Court concludes that although we ultimately found in M.E.P.'s favor, First Graphics undertook a reasonable pre-filing inquiry. n1 *See, e.g., Hoffmann-LaRoche, Inc. v. Invamed, Inc., 213 F.3d 1359 (Fed. Cir. 2000)*(plaintiffs conducted reasonable pre-filing inquiry that suggested patents were infringed although plaintiff later voluntarily dismissed claim for lack of merit).

n1 In its Reply, M.E.P. suggests that First Graphics should have known that it could purchase a fully-functioning $ 6,000 copy of AutoSprink, use it, and then return it for a refund. M.E.P.'s Reply in Support of Motion for Fees at 2. In support of its argument, M.E.P. attaches an AutoSprink advertisement that includes this money-back guarantee in fine print. However, M.E.P. has provided no evidence as to when and how this advertisement was circulated, and we decline to find that First Graphics should have availed itself of this option.

[*7]

M.E.P. next attempts to establish that First Graphics "knew" it had filed a frivolous lawsuit by pointing to statements made by the company during the pendency of its patent application at the Patent Office. During the application process, First Graphics attempted to distinguish its patents from prior art by representing to the Patent Office that, unlike the patented software, the prior art did not "compare ... [the] layout to determine whether or not it complies with a standard or even whether or not it will work." M.E.P.'s Motion for Fees, Exhibit A. First Graphics further stated to the Patent Office that its patented invention evaluates a "system's compliance to a selected standard such as a building code." *Id.* M.E.P. now argues that First Graphics "knew" that AutoSprink did not infringe its patents because AutoSprink "does not compare, determine, or evaluate anything -- it just draws the design entered by the user," and that such activity was disclaimed by First Graphics to the Patent Office.

M.E.P.'s Motion for Fees at 4. However, M.E.P. misstates First Graphics' litigation position -- it argued that AutoSprink did indeed compare and evaluate data via the "3-point wizard" [*8] feature. Though we ultimately found in its favor on this issue, M.E.P. is not entitled to attorneys' fees simply because its argument prevailed.

M.E.P. finally argues that First Graphics acted in bad faith because it refused to accept a settlement offer from M.E.P. or agree with M.E.P.'s position of non-infringement. As First Graphics correctly notes, "it is not the general practice of an advocate to blithely follow the statements of his opponent as to the adequacy of his own case." *London v. Carson Pirie Scott & Co., 1993 U.S. Dist. LEXIS 9876,* No. 85 C 9712, *1993 WL 276778* (N.D. Ill., July 20, 1993). Further, simply because M.E.P. considered its settlement offer to be favorable does not make it so, and the Court does not find that First Graphics' rejection of the offer evidences bad faith. M.E.P.'s arguments on this score are rejected.

II. *Misconduct During Litigation*

M.E.P. also argues that an attorneys' fees award is warranted because First Graphics engaged in various misdeeds prior to and during the pendency of this lawsuit. M.E.P. first points to a "letter to the editor" from First Graphics' counsel, Arne Olson, that was published in FPC Magazine -- a leading trade publication. [*9] The letter appeared prior to the commencement of this lawsuit and stated, in part:

> We recently read an article published in the May 1999 edition of *FPC/Fire Protection Contractor* about the AutoSprink fire sprinkler CAD computer program by M.E.P. CAD. ... We are writing simply to inform you that [First Graphics] is the owner of United States Patent Nos. 5,227,983; 5,557,537; and 5,808,905. These patents cover computer programs that automatically design complete fire sprinkler systems.

M.E.P.'s Motion for Fees, Exhibit C. M.E.P. argues that this letter constituted a threat to the industry to stay away from AutoSprink and asserts, citing *International Industries and Developments v. Farbach Chemical Company, 241 F.2d 246 (6th Cir. 1957),* that this threat alone warrants a fee award. In *International Industries,* the plaintiff sent 8,000 letters to manufacturers, dealers, and retailers of dip-type liquid silver cleaners. *Id. at 248.* The letter informed its recipients that the plaintiff held patent rights in these type of cleaners and listed the manufacturers who were licensed to produce the product. *Id.* The letter concluded by [*10] asserting that "any persons, firms or corporations manufacturing, advertising, selling or distributing dip-type silver cleaning liquids or powders in violation [of the patents] do so at their peril. Any infringement will be liable to prosecution." *Id.* The Sixth Circuit found that the average recipient of this letter would understand it to mean that he would be sued if he sold silver cleaners manufactured by anyone other than the listed entities. *Id.* The Court's interpretation was supported by evidence that numerous customers asked the defendant whether it was "licensed" under plaintiff's patent, and many ceased purchasing the defendant's products after receiving the letter. *Id.*

As an initial matter, we do not agree that *International Industries* stands for the proposition that any communication to the trade as a whole warrants an attorneys' fee award. Indeed, the District Court in *International Industries* based its fee award also on evidence that the plaintiff never examined the defendant's competing product prior to or after filing suit; had no good faith basis for filing the suit; and misled the court as to the existence of issues of fact in response to a motion [*11] for summary judgment. *See International Industries and Developments v. Farbach Chemical Company, 145 F. Supp. 34 (S.D. Ohio 1956), aff'd, 241 F.2d 246 (6th Cir. 1957).* Moreover, the letter in this case is distinguishable from the *International Industries* letters. In this case, the letter was not sent directly to any purchasers or distributors of AutoSprink, and it contained no overt threat that any buyer of AutoSprink would be sued. Moreover, unlike the defendant in *International Industries,* M.E.P. has offered no evidence that any of its customers ever saw or were troubled by the letter, or that the letter had any impact on its business at all.

M.E.P. additionally argues that First Graphics' issuance of subpoenas to four of its customers constitutes misconduct sufficient to support a fee award. Though the Court ultimately quashed these subpoenas, we do not conclude that their mere issuance creates an exceptional case. The subpoenas were limited in number and targeted only those companies that M.E.P. itself identified through "testimonials" in its marketing materials.

M.E.P. finally asserts that First Graphics attempted to procure information [*12] directly from M.E.P. representatives after this lawsuit had been filed. Specifically, M.E.P. asserts that David Hoeft worked the M.E.P. booth at a National Fire Protection Association ("NFPA") trade show in Colorado in May 2000 and was approached by a gentleman who asked questions about AutoSprink. Hoeft Affidavit, PP 4, 5. Hoeft further asserts that he met with First Graphics' owner Charles Hines and attorney Arne Olson in June 2000, and that Olson "seemed familiar" at that time. Hoeft Affidavit, P 7. Hoeft states that he be-

lieves that it was Olson who approached him in Denver. *Id.* In response, Olson provides an affidavit to the effect that he has never attended an NFPA trade show and that he was in Chicago on the days in question. Olson Affidavit, P 17. Based on the evidence provided, the Court does not find that M.E.P. has met its evidentiary burden of showing litigation misconduct by clear and convincing evidence.

In short, the Court determines that M.E.P. has failed to demonstrate by clear and convincing evidence that this case warrants "exceptional" status. Accordingly, we deny M.E.P.'s motion for fees pursuant to *35 U.S.C. § 285.*

Conclusion [*13]

For the foregoing reasons, M.E.P.'s Motion for Attorneys' Fees [item # 96-1] is denied.

Date: August 13, 2002

MATTHEW F. KENNELLY

United States District Judge

EXHIBIT F

Westlaw.
Not Reported in F.Supp.2d
Not Reported in F.Supp.2d, 2006 WL 616292 (E.D.Pa.), 2006-1 Trade Cases P 75,158
(Cite as: Not Reported in F.Supp.2d)

C

Briefs and Other Related Documents

In re Wellbutrin SR Antitrust LitigationE.D.Pa.,2006.
United States District Court,E.D. Pennsylvania.
In re WELLBUTRIN SR ANTITRUST LITIGATION
SHEET METAL WORKERS LOCAL 441 Health and Welfare Plan, et al.
v.
GLAXOSMITHKLINE, PLC, et al.
MEDICAL MUTUAL OF OHIO, INC.
v.
GLAXOSMITHKLINE PLC and Smithkline Beecham Corp.
No. Civ.A. 04-5525, Civ.A. 04-5898, Civ.A. 05-396.

March 9, 2006.

Daniel E. Gustafson, Heins Mills & Olson, Minneapolis, MN, Dianne M. Nast, Roda & Nast, PC, Lancaster, PA, Arnold Levin, Fred S. Longer, Levin, Fishbein, Sedran & Berman, Philadelphia, PA, Joseph H. Meltzer, Schiffrin and Barroway, L.L.P., Radnor, PA, Joshua H. Grabar, Bolognese & Associates, LLC, Philadelphia, PA, Ann D. White, Ann D. White Law Offices, P.C., Jenkintown, PA, E. McCord Clayton, Philadelphia, PA, John W. Turner, Neal S. Manne, Susman Godfrey LLP, Dallas, TX, Mark D. Fischer, Mark M. Sandmann, Rawlings & Assoc., Louisville, KY, Shawn Jonathan Rabin, Dallas, TX, William C. Carmody, William Christopher Carmody, P.C., Dallas, TX, for Plaintiffs.
Amy R. Mudge, Cathy A. Hoffman, David P. Gersch, Kenneth A. Letzler, William J. Baer, Arnold & Porter LLP, Washington, DC, Timothy A. Thelen, Triangle Park, NC, Angela Kweon, Leslie E. John, Mark Steven Stewart, Ballard Spahr Andrews & Ingersoll LLP, Philadelphia, PA, for Defendants.
H. Holden Brooks, Arnold & Porter, Washington, DC, for Plaintiffs and Defendants.

MEMORANDUM AND ORDER

KAUFFMAN, J.

***1** THIS DOCUMENT RELATES TO: ALL ACTIONS

The Motion to Dismiss now before the Court concerns four distinct actions: *SAJ Distributors, Inc. v. Smithkline Beecham* (04-Cv-5525), *Meijer, Inc. v. Glaxosmithkline PLC* (04-Cv-5643), *Sheet Metal Workers Local 441 Health & Welfare Plan v. Glaxosmithkline PLC* (04-Cv-5898) and *Medical Mutual of Ohio, Inc. v. Glaxosmithkline PLC* (05-Cv-396). In each of those actions, Plaintiffs allege that Defendants Glaxosmithkline and its subsidiary Smithkline Beecham Corporation (together "GSK") have acted unlawfully to block the marketing of generic versions of GSK's depression drug Wellbutrin SR, in violation of federal antitrust laws.

SAJ Distributors, Inc. v. Smithkline Beecham and *Meijer, Inc. v. Glaxosmithkline PLC* [FN1] are putative class actions, both brought on behalf of a class of direct purchasers, a term which the complaints define as "all persons or entities in the United States that purchased Wellbutrin SR directly from GSK during the period of January 24, 2002 to a date to be determined." *See* Class Action Complaint (04-Cv-5525) ("the Saj Complaint") ¶ 108. *Sheet Metal Workers Local 441 Health & Welfare Plan v. Glaxosmithkline PLC* is also a putative class action; the plaintiffs therein, however, seek to represent the class of "indirect purchasers," which is defined as "all persons and entities in the United States who, at any time from July 1, 2001 to the present purchased Wellbutrin SR, Zyban and/or their generic equivalents in the United States for purposes other than resale." *See* Class Action Complaint (04-Cv-5898) (the "Sheet Metal Complaint") ¶ 21. In the final action, *Medical Mutual of Ohio, Inc. v. Glaxosmithkline PLC,* the plaintiff is a "third-party payor for Wellbutrin SR." *See* Plaintiff's Original Complaint (05-Cv-396) (the "Medical Mutual Complaint") ¶¶ 7-8.

FN1. These actions have been consolidated. *See SAJ Distributors, Inc. v. Smithkline Beecham,* No. 04-5525 (E.D.Pa. Jan. 27, 2005).

Now before the Court is GSK's Motion to Dismiss the Complaints. For the reasons that follow, the Mo-

tion will be granted in part and denied in part.

I. BACKGROUND

These actions arise from GSK's efforts to use certain patents it has obtained to prevent its competitors from marketing generic versions of the depression drug Wellbutrin. Accepting the allegations of the Complaints as true, the pertinent facts are as follows.

A. *GSK's Bupropion Patents*

GSK's predecessor secured the first of the Wellbutrin patents, which was issued as U.S. Patent No. 3,819,706 (the " '706 Patent"), in 1974. That patent was for a substance known as bupropion hydrochloride ("bupropion"), which was known to act as an antidepressant. Sheet Metal Complaint ¶ 45. Medical Mutual Complaint ¶ 25. In the mid-1980's, the United States Food & Drug Administration ("FDA") granted GSK's predecessor [FN2] approval to manufacture, market and sell bupropion under the brand name Wellbutrin. Sheet Metal Complaint ¶ 46. Wellbutrin was designed to release more than 75 percent of the bupropion contained in each tablet within approximately forty-five minutes of ingestion. For that reason, it was generally prescribed to be taken three to four times per day. *Id.* ¶ 47.

FN2. The Court will refer to GSK' predecessor and GSK interchangeably.

***2** The '706 Patent expired in mid-1991. Soon thereafter, GSK developed a sustained release version of bupropion, which uses an excipient known as hydroxypropyl methycellulose ("HPMC") to issue the bupropion into the gastrointestinal tract at sustained intervals .[FN3] This sustained release mechanism reduces the number of doses necessary, such that a typical user of the sustained release bupropion need only take one or two doses per day. *Id.* ¶ 49.

FN3. An excipient is a usually inert substance used as a vehicle for a drug.

In August 1993, GSK filed an application with the United States Patent and Trademark Office ("PTO") seeking patent protection for the sustained release bupropion tablets it had developed. *Id.* ¶ 50. The application was rejected. The patent examiner found that the claim for patent protection was overly broad insofar as it would have covered any sustained release mechanism for bupropion. The patent claims, he wrote, needed to be limited to the specific sustained release agent GSK's predecessor had developed: HPMC. *Id.* ¶ 52. In response to the PTO's objections, GSK amended its claims "to recite that the tablet required HPMC." *Id.* ¶ 53. Once these amendments were made, the PTO issued a Notice of Allowability indicating that "the PTO's previous rejection of the claims would be withdrawn based on the addition of the HPMC limitation." *Id.* ¶ 57.

On June 27, 1995, the PTO issued to GSK Patent No. 5,427,798 (the " '798 Patent") which was entitled "Controlled sustained release tablets containing bupropion." *Id.* ¶ 58. Plaintiffs allege that at the time the limiting amendments to the patent claims were made, GSK was aware of the existence of other excipients capable of administering bupropion on a sustained release basis, including hydroxypropyl cellulose ("HPC") and polyvinyl alcohol ("PVA"). *Id.* ¶ 64.

In October 1996, the FDA granted final approval for Wellbutrin SR, the sustained release version of Wellbutrin. *Id.* ¶ 66. In mid-1997, GSK brought Wellbutrin SR to market. Several months later, GSK also began marketing Zyban, which is chemically identical to Wellbutrin SR, but marketed for smoking cessation rather than depression.[FN4] *Id.* ¶¶ 2, 67.

FN4. Defendant has assigned the two drugs different names purely for marketing purposes. For the twelve months ending June 30, 2002, domestic sales of Wellbutrin SR generated revenues in excess of $1.3 billion. Domestic sales of Zyban were $83 million for the same period.

B. *Attempts to Bring Generic Versions of Wellbutrin to Market*

Ordinarily, a company wishing to market a new drug must seek the approval of the FDA by completing a New Drug Application ("NDA"). However, the enactment of the Drug Price Competition and Patent

Term Restoration Act in 1984 (the "Hatch-Waxman Act" or the "Act") carved out an exception to that general rule for manufacturers seeking to market generic drugs. Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat. 1585, codified at 21 U.S.C. § 355(j). Under 21 U.S.C. § 355(j), a generic company may file an Abbreviated New Drug Application ("ANDA") which relies on the FDA's previous findings of safety and efficacy. The applicant must include in the ANDA a certification that the proposed generic drug would not infringe existing valid patents by its manufacture, use, or sale. 21 U.S.C. § 355(j)(2)(A)(vii). If the generic applicant claims that a relevant patent is invalid or will not be infringed by its product, it must so certify to the FDA and notify the patent-holder. 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (commonly known as "paragraph IV certification"); 21 U.S.C. § 355(j)(2)(B)(I). The patent-holder then has forty-five days within which to bring a patent infringement suit against the applicant. If the patent-holder brings such a suit, the FDA's approval of the ANDA is automatically delayed for thirty months or until the patent is declared invalid or not infringed ("30-month stay"). 21 U.S.C. § 355(j)(5)(B)(iii).

***3** Additionally, the Act provides a significant incentive to generic-drug manufacturers who file the first ANDA ("first filer"): a 180-day period of market exclusivity before subsequent ANDA filers can enter the market. 21 U.S.C. § 355(j)(5)(B)(iv). The 180-day period begins to run when the first filer commercially markets the generic drug or when the court declares the existing patent invalid. *Id.*

Beginning in August 1999, several generic-drug manufacturers, including Andrx Pharmaceuticals ("Andrx"), Eon Labs ("Eon"), Impax Laboratories ("Impax"), Excel Pharmaceuticals ("Excel") and Watson Laboratories ("Watson") sought approval to market generic versions of Wellbutrin SR. Each company filed an ANDA pursuant to 21 U.S.C. § 355(j) and gave GSK notice of its intention to introduce a generic version of Wellbutrin SR. GSK's response was the same in each case: it filed a patent infringement suit, thus triggering the 30-month stay of the FDA's approval of the ANDAs. The effect of that stay was to allow GSK to maintain its monopoly over Wellbutrin SR until either the 30 month period had expired or the generic drug manufacturer obtained a judgment of non-infringement.

C. *The Underlying Infringement Suits*

GSK pursued the Eon and Impax infringement suits simultaneously.[FN5] The issues in the two cases were virtually identical, as both the Eon and Impax drugs used the same excipient-HPC-as a release mechanism. Both Eon and Impax filed summary judgment motions in their respective cases. Eon's motion was decided first: on August 13, 2002, the district court issued a memorandum and order denying summary judgment on the grounds that GSK had raised a genuine issue of fact as to "the foreseeability of HPC as a sustained release agent." *Glaxo Wellcome, Inc. v. Eon Labs Mfg.*, 2002 WL 1874831, at *5 (S.D.N.Y. Aug.13, 2002). Just over a week later, the district court hearing the Impax case reached the opposite result-that Impax was entitled to summary judgment. *Glaxo Wellcome, Inc. v. Impax Laboratories, Inc.*, 220 F.Supp.2d 1089 (N.D.Cal.2002). GSK subsequently appealed the adverse judgment to the Federal Circuit.

> FN5. For standing reasons, Plaintiffs' claims are based only on the Eon and Impax actions.

In November 2003, while the Impax appeal was pending before the Federal Circuit, Eon announced that it was taking steps to bring its generic version of Wellbutrin SR to market, a move which was now possible because the thirty-month stay triggered by GSK infringement action had expired. GSK responded by moving for a Temporary Restraining Order ("TRO"), which was granted on November 26, 2003, and then extended on December 12, 2003. *See Glaxo v. Eon,* No. 00-9089 (S.D.N.Y. Nov. 26, 2003) and (S.D.N.Y. Dec. 12, 2003) (attached as Exhs. 24 and 25 to GSK's Memorandum in Support of Motion to Dismiss ("GSK's Memo")). While the TRO was still in place, the district court held a bench trial. At the conclusion of the trial, the district court converted the TRO into a preliminary injunction. *Id.* No. 00-9089 (S.D.N.Y. Dec. 29, 2003). Several days later, Eon moved to stay the injunction, which the district court denied on January 7, 2004. The court explained that it

was keeping the injunction in place in order to "preserve the status quo," i.e., GSK's monopoly over Wellbutrin SR, until the court was able to render a final decision on the merits. *See Id.,* No. 00-9089 (S.D.N.Y.) (trial tr. Jan. 7, 2004 at 17-19).

***4** Eon immediately appealed the preliminary junction to the Federal Circuit. The turnaround was short. On January 12, 2004, the Federal Circuit entered an Order staying the preliminary injunction. *Eon,* App. No. 04-1169 (Fed.Cir. Jan. 12, 2004) (attached as Exh. 28 to GSK's Memo). Eon promptly began shipping its product.

On January 29, 2004, the Federal Circuit decided GSK's appeal in the Impax case. As noted above, the district court in that case had granted Impax summary judgment. The Federal Circuit affirmed that decision. *See* Glaxo Wellcome, Inc. v. Impax Labs., Inc., 356 F.3d 1348 (Fed.Cir.2004). The Federal Circuit's decision against GSK in *Impax* had an obvious bearing on proceedings in the Eon matter, where the issues were nearly identical. Recognizing this, GSK voluntarily dismissed the Eon action. The dismissal took place before the trial judge rendered a decision on the merits.

D. *The '994 Patent*

GSK obtained U.S. Patent No. 4,687,660 (the " '660 patent") on August 18, 1987. Saj Complaint ¶ 28. At some point thereafter, the '660 patent was "being reexamined in response to the discovery of two prior art patents that, when combined" rendered the '660 patent unpatentable. *Id.* ¶ 80. In order to preserve its monopoly over the subject matter of the '660 patent, GSK applied to have the patent reissued.[FN6] It succeeded and on July 14, 1992, the '660 patent was reissued as U.S. Patent No. RE33,994 ("the '994 patent"). *Id.* ¶ 28. The reissued patent "was drawn to pharmaceutical compositions that resulted in a controlled release of bupropion in a simulated gastric buffer. The Saj complaint alleges that GSK fraudulently misrepresented facts material to patentability to obtain the '994 patent." *Id.* ¶ 76.

FN6. A reissue patent examination is conducted when requested by the patent holder to remedy a defect in the patent that makes it fully or partially inoperative or invalid. Saj Complaint ¶ 78.

E. *The Present Lawsuit*

The gravamen of Plaintiffs' Complaints is that GSK's infringement lawsuits constituted sham litigation in violation of state and federal antitrust laws. They contend that the lawsuits were frivolous, that GSK knew they were frivolous, and that GSK used the litigation to unlawfully extend its monopoly for the period of the stay.[FN7] To that end, Plaintiffs have brought an assortment of federal and state law claims. The Saj Complaint alleges violations of § 2 of the Sherman Antitrust Act, 15 U.S.C. § 2 (the "Sherman Act"). The Sheet Metal Complaint seeks injunctive and declaratory relief under § 16 of the Clayton Antitrust Act, 15 U.S.C. § 26 (the "Clayton Act") for violations of § 2 of the Sherman Act (count one); in addition, it claims violations of state antitrust laws (count two), that GSK is liable for unfair and deceptive trade practices (count three), and unjust enrichment (count four). Finally, like the Sheet Metal Complaint, the Medical Mutual Complaint seeks injunctive relief under § 16 of the Clayton Act based on violations of § 2 of the Sherman Act (count one); it also claims violations of state antitrust laws (count two) and state consumer fraud and unjust enrichment laws (count three).

FN7. The Saj Complaint alone seeks relief based on GSK's allegedly fraudulent prosecution of the '994 patent.

***5** Defendants have moved to dismiss all the Complaints under Fed.R.Civ.P. 12(b)(6) for failure to state a claim upon which relief may be granted.

II. LEGAL STANDARD

When deciding a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), the Court may look only to the facts alleged in the complaint and its attachments. *Jordan v. Fox, Rothschild, O'Brien & Frankel,* 20 F.3d 1250, 1261 (3d Cir.1994). The Court must accept as true all well-pleaded allegations in the complaint and view them in the light most favorable to the plaintiff. *Angelastro v. Prudential-*

Bache Sec., Inc., 764 F.2d 939, 944 (3d Cir.1985). A Rule 12(b)(6) motion will be granted only when it is certain that no relief could be granted under any set of facts that could be proved by the plaintiff. *Ransom v. Marrazzo*, 848 F.2d 398, 401 (3d Cir.1988).

III. GSK'S IMMUNITY UNDER NOERR-PENNINGTON

The central issue in this Motion to Dismiss is the applicability of the *Noerr-Pennington* doctrine (*"Noerr-Pennington"*), which generally provides immunity from antitrust liability to those who petition the government for redress. This immunity serves to protect "from the Sherman [Antitrust] Act a concerted effort to influence public officials regardless of intent or purpose." *Mine Workers v. Pennington*, 381 U.S. 657, 670, 85 S.Ct. 1585, 14 L.Ed.2d 626 (1965). GSK argues that its infringement suits qualify for *Noerr-Pennington* immunity and that Plaintiffs' antitrust claims, both state and federal, should be dismissed.

A. *The Sham Exception to Noerr-Pennington*

Plaintiffs acknowledge that lawsuits are ordinarily protected activity under *Noerr-Pennington,* but argue that the infringement actions at issue here are subject to an exception. The Supreme Court has established a "sham exception" to *Noerr-Pennington* immunity. "Activity 'ostensibly directed toward influencing government action' does not qualify for ... immunity if it 'is a mere sham to cover ... an attempt to interfere directly with the business relationships of a competitor." ' *Professional Real Estate Investors, Inc. v. Columbia Pictures Industry, Inc.*, 508 U.S. 49, 51, 113 S.Ct. 1920, 123 L.Ed.2d 611 (1993) (quoting *Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 144, 81 S.Ct. 523, 5 L.Ed.2d 464 (1961)). Plaintiffs contend that the GSK patent infringement suits constitute "sham litigation" and thus fall under the exception.

Accordingly, the Court must determine whether the GSK infringement suits were "protected activity" under *Noerr-Pennington* or whether, as Plaintiffs claim, they are subject to the "sham litigation" exception. *Professional Real Estate* is the key case discussing that exception. There, the Supreme Court set out a two-part test: the antitrust defendant's immunity gives way only if the plaintiff demonstrates that (1) the underlying lawsuit on which the antitrust suit is based is "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits[;]" and (2) "the lawsuit conceals "an attempt to interfere directly with the business relationships of a competitor, through the use of the governmental *process*-as opposed to the outcome of that process-as an anticompetitive weapon[.]" 508 U.S. at 60-61 (emphasis in original) (quoting *Noerr*, 365 U.S. at 144 and *Columbia v. Omni Outdoor Advertising, Inc.*, 499 U.S. 365, 380, 111 S.Ct. 1344, 113 L.Ed.2d 382 (1991)).

***6** The Court analogized the "objectively baseless" standard in the first prong of the test to the concept of "probable cause as understood and applied in the commonlaw tort of wrongful civil proceedings[.]" *Id.* at 62. "Probable cause to institute civil proceedings," the Court explained, "requires no more than a 'reasonable belief that there is a chance that a claim may be held valid upon adjudication[.]" ' *Id.* (quoting *Hubbard v. Beatty & Hyde, Inc.*, 343 Mass. 258, 262, 178 N.E.2d 485, 488 (1961)). Conversely, in order to overcome *Noerr-Pennington* immunity, the antitrust plaintiff must demonstrate that the defendant who brought the underlying suit could not have held such a belief. Thus, the first prong of the test, with its emphasis on the *reasonable* litigant, is concerned with the objective merits of the lawsuit at issue. The second prong, in contrast, focuses on the antitrust defendant's subjective intentions.

GSK contends that Plaintiffs are unable to satisfy the first prong of the test-that, in other words, they cannot establish that the Eon and Impax suits were objectively baseless. The question before the Court is thus whether GSK had probable cause to bring the infringement actions, i.e., whether it could reasonably have believed that its infringement claims might have been "held valid upon adjudication." *Id.*

B. *The Probable Cause Determination*

The answer to that question plainly depends on (1) the facts GSK faced when it filed the suits, (2) the

governing legal principles, and (3) how those principles apply to the facts. *See* Professional Real Estate, 508 U.S. at 67 (Souter, J., concurring) (stating that the standard is whether "on the undisputed facts and the law as it stood when Columbia filed its suit, a reasonable litigant could realistically have expected success on the merits."); Restatement (Second) of Torts § 675, cmt. a (1977) ("[T]he claimant's mistaken belief in the possible validity of his claim may be a mistake as to the facts upon which the claim is based or a mistake as to the possible validity of his claim under the facts reasonably believed to exist.").

Because this is a Motion to Dismiss, the Court must base the probable cause determination on the facts alleged in Plaintiffs' Complaints. That is, the Court must assume that the facts GSK confronted when it initiated the Eon and Impax cases are those Plaintiffs have alleged in the Complaints. GSK contends that the Court need not accept the allegations in the Complaints as true at this stage. It urges the Court to make factual findings that deviate from the allegations in the Complaints based on trial transcripts and opinions from the underlying infringement actions, of which, it argues, the Court may take judicial notice. *See* GSK's Memo at 24.

GSK is correct that the Court may take judicial notice of the opinions filed in the underlying actions; however, the scope of that notice is subject to important limitations. The Court may take judicial notice only of the "existence of the opinion, which is not subject to reasonable dispute over its authenticity." Southern Cross Overseas Agencies, Inc. v. Wah Kwong Shipping Group Ltd., 181 F.3d 410, 426 (3d Cir.1999). The Court may *not,* however, make factual findings in this case based on the facts recited in the opinions of other courts. *Id.*

*7 It follows that for the purposes of this Motion to Dismiss, GSK cannot invoke the record in the underlying infringement actions to challenge factual allegations in the Complaints. The Court's probable cause analysis must therefore be based exclusively on the allegations in Plaintiffs' Complaints, regardless of whether those allegations are consistent with the factual findings of other courts. Jarrow Formulas, Inc. v. Int'l Nutrition Co., 175 F.Supp.2d 296, 311 (D.Conn.2001) ("Here, all that is required is that the complaint allege facts, which, if proven, show that the defendant is not entitled to *Noerr-Pennington* immunity under the sham litigation exception."); Skinder-Strauss Assocs. v. Mass. Continuing Legal Educ., Inc., 870 F.Supp. 8, 10 (D.Mass.1994) ("Because [the defendant's] counterclaims allege that the lawsuit filed by [the plaintiff] is objectively baseless and conceals an attempt to interfere directly with the business relationships of a competitor, the counterclaims adequately state a claim and should not be dismissed under Fed.R.Civ.P. 12(b)(6).")

The next question in the probable cause inquiry is how those facts would have been analyzed under the governing law. The Court must, in other words, consider whether GSK could reasonably have believed that the facts as Plaintiffs have alleged them gave rise to a claim for infringement against Eon and Impax.

It is thus necessary to examine GSK's theory of infringement. As noted above, GSK argued in the lawsuits that the Eon and Impax drugs infringed on the '798 patent. The '798 patent was limited to drugs that used the excipient HPMC as a release agent for bupropion. Because the Eon and Impax drugs employ a different excipient, HPC, as a release agent, GSK was foreclosed from claiming literal infringement. Instead, it was forced to rely on the doctrine of equivalents.

The doctrine of equivalents is essentially an expansion of the intellectual property rights of a patent holder; it allows a claim not only for those ideas described by the literal terms of the patent, but any "equivalents" as well. Festo Corp. v. Shoketsu Kinzoku Kogyo Kbushiki Co., 535 U.S. 722, 732, 122 S.Ct. 1831, 152 L.Ed.2d 944 (2002) ("Festo VIII"). An equivalent is a product or process developed by a would-be competitor of the patent-holder which makes "unimportant and insubstantial changes and substitutions in the patent which, though adding nothing, would be enough to take the copied matter outside the claim, and [absent the doctrine of equivalents] outside the reach of law." Graver Tank & Mfg. Co. V. Linde Air Products Co., 339 U.S. 605, 607, 70 S.Ct. 854, 94 L.Ed. 1097 (1950).[FN8]

> FN8. The Supreme Court has explained that estoppel doctrine is essential if patents are to serve their purpose of providing an incentive for innovation: "If patents were always interpreted by their literal terms, their value would be greatly diminished. Unimportant and insubstantial substitutes for certain elements could defeat the patent, and its value to inventors could be destroyed by simple acts of copying." *Festo VIII*, 535 U.S. at 732.

GSK argues that its infringement suits against Eon and Impax were not a sham because it had a good faith argument based on the doctrine of equivalents: namely, that while the Eon and Impax drugs do not literally infringe the '798 patent, they are equivalents to the claimed subject matter, and consequently infringe by equivalence.

Plaintiffs, on the other hand, contend that GSK's reliance on the doctrine of equivalents is "objectively baseless." Their argument is rooted in a limitation to equivalence protection which courts have termed "the doctrine of prosecution history estoppel." The doctrine of prosecution history estoppel becomes relevant when a patent application fails to meet a statutory requirement for patentability, and is consequently rejected by the PTO. If "the patentee responds to the rejection by narrowing his claims, this prosecution history estops him from later arguing that the subject matter covered by the original, broader claim was nothing more than an equivalent." *Festo VIII*, 535 U.S. at 727. Here, Plaintiffs contend that GSK's decision to amend its original formulation of the '798 patent so as to narrow the claim to a drug that used HPMC as its sustained release mechanism estopped GSK from arguing for the "equivalence" of drugs like Eon's and Impax's, which deploy other sustained release agents. Accordingly, they argue, the doctrine of prosecution history estoppel would have proven an insuperable barrier to the Eon and Impax suits.

***8** GSK responds that the law governing prosecution history estoppel was unsettled at the time it filed the suits. The resulting ambiguity, it argues, left open the possibility that the narrowing amendments did not bar GSK from claiming the Eon and Impax drugs as equivalents. In order to test that assertion, the Court must examine the state of the law at the time GSK filed the infringement suits. During the 1980's and 1990's, the Federal Circuit articulated two competing and inconsistent rules as to the scope of the doctrine of prosecution history estoppel. *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki*, 234 F.3d 558, 574 (Fed.Cir.2000) ("Festo VII") (acknowledging inconsistency). The more prevalent of the two was known as the flexible bar rule, according to which the doctrine of prosecution history estoppel extends only to subject matter the patent holder relinquished during the prosecution. Under that approach, a court would determine whether a patent holder is estopped from claiming his competitor's product as an equivalent by looking to the subject matter the patent holder surrendered when it adopted the narrowing amendments. If the competitor's product falls within the surrendered subject matter, estoppel applies. *See Litton Sys., Inc. v. Honywell, Inc.*, 140 F.3d 1449, 1455-57 (Fed.Cir.1998) (holding that "an estoppel only bars recapture of that subject matter actually surrendered during prosecution."); *Hughes Aircraft Co. v. United States*, 140 F.3d 1470, 1476-77 (Fed.Cir.1998) (holding that in order to determine the scope of the estoppel, there must be a determination as to the exact "subject matter the patentee actually surrendered.").

The second approach, known as the "complete bar rule," treated a narrowing amendment adopted by the patent holder to act as a complete bar to claiming equivalents. *See, e.g., Kinzenbaw v. Deere Co.*, 741 F.2d 383, 391 (Fed.Cir.1984). That is, once the patent holder adopts the narrowing amendments, the patent is effectively limited to its literal terms and the patent holder may no longer claim infringement by equivalence.

The Federal Circuit attempted to resolve the uncertainty with its decision in *Festo VII*, which expressly adopted the complete bar rule. *Festo VII*, 234 F.3d at 574. The flexible bar rule, it explained, was not workable and could not be consistently applied. The bright-line approach represented by the complete bar rule was the only feasible option. *Id.* The matter did not end there, however. The Supreme Court granted *certiorari*, and, on May 28, 2002, in a unanimous de-

cision, reversed, holding that, despite the Federal Circuit's misgivings, the flexible bar rule is the correct approach. *See* Festo VIII, 535 U.S. 722, 737, 122 S.Ct. 1831, 152 L.Ed.2d 944 (holding that the estoppel doctrine's "reach requires an examination of the subject matter surrendered by the narrowing amendments.") Thus, held the Court, so long as the competitor's product falls within "the territory between the original claim and the amended claim[,]" the patentholder is barred from bringing an infringement claim. Id. at 740.

***9** The law governing the application of the flexible bar rule, i.e., how a court determines what subject matter the patent holder's amendments surrender, has also undergone important changes. At the time GSK filed its infringement suits, "the standard for determining whether subject matter has been relinquished is whether one of ordinary skill in the art would objectively conclude from the prosecution history that an applicant surrendered it." Litton Sys., Inc. v. Honeywell, Inc., 140 F.3d 1449, 1462 (Fed.Cir.1998) (citing Marl I Mktg. Corp. v. R.R. Donnelley & Sons Co., 66 F.3d 285, 291 (Fed.Cir.1995)). Then, in *Festo VIII*, the Supreme Court provided new guidance on the question. It held that "the patentee bears the burden of showing that the amendment does not surrender the particular equivalent in question." 535 U.S. at 740. However, the patentee can rebut that presumption by establishing that one of the following situations applies: "The equivalent may have been unforeseeable at the time of the application; the rationale underlying the amendment [bears] no more than a tangential relation to the equivalent in question; or there [is] some other reason suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question." Id. at 740-41.

As noted above, GSK's argument is that the changes in the law governing prosecution history estoppel show that at the time it filed the infringement suits, the law had not yet solidified to the point that it was clear that GSK was estopped from claiming the Eon and Impax drugs as equivalents. Uncertainty in the law by itself, however, is not sufficient to create probable cause. Rather, for probable cause to exist, the range of the uncertainty must extend far enough to render viable a legal rule that would allow the plaintiff to prevail. That is not the case here.

GSK filed its infringement suit against Impax on September 28, 2000. Its suit against Eon was filed two months later on November 29, 2000, the same day that the *Festo VII* decision was announced. At that point, there was still some uncertainty as to whether the flexible bar rule or the complete bar rule was the governing law. Nevertheless, it was clear that, *at the very least,* the doctrine applied to all subject matter the patent holder had relinquished via narrowing amendments during prosecution. The only outstanding question was whether the scope of estoppel would reach further.

Thus, at the time the suits were filed, any reasonable litigant would have understood that if the Eon and Impax drugs fell within the subject matter GSK relinquished by adopting the narrowing amendments, GSK would not be able to claim them as equivalents. The only remaining question therefore is whether by narrowing its claim in response to the patent examiner's objections, GSK surrendered the right to claim as equivalents tablets that used excipients other than HPMC to administer the bupropion over time.

***10** The facts Plaintiffs have alleged, which the Court must assume to be true for the purposes of this Motion, compel an affirmative answer to that question. According to the Complaints, GSK's initial patent application for sustained release bupropion was rejected for lack of enablement. The PTO examiner found that HPMC was "critical for the controlled and/or sustained release and should be incorporated into the independent claims. The disclosure of a single species does not provide a basis for disclosing a generic concept." *See* Sheet Metal Complaint at ¶ 52; Saj Complaint at ¶ 35; Medical Mutual Complaint at ¶ 33. The examiner's conclusion thus was that GSK was entitled to protection only for the specific means of achieving the sustained release bupropion that it had devised, namely the excipient HPMC. Sheet Metal Complaint ¶ 56. In response to the examiner's findings, GSK "submitted narrowing amendments to the patent examiner. These amendments narrowed the scope of the claims from covering all pharmaceutical means for achieving a specified release rate of bupro-

pion to covering only HPMC, the single controlled release means divulged in the patent disclosure." *See* Saj Complaint at ¶ 37; Sheet Metal Complaint at ¶¶ 53-55.

HPC, the excipient that the Eon and Impax generic drugs use to achieve sustained release, "had been recognized as a release controlling substitute excipient for HPMC since before the prosecution of the application that would issue as the '798 patent." *See* Saj Complaint at ¶ 38. "GSK knew that HPC was a substitute for HPMC" when it agreed to the narrowing amendments. *See* Saj Complaint at ¶ 43; Sheet Metal Complaint at ¶ 64.

These facts render immaterial the changes in the law governing how a court determines what subject matter a patent holder has surrendered during patent prosecution. Under both the Federal Circuit test that governed when the infringement suits were filed and the three factor test announced in *Festo VIII* that succeeded it, the allegations in the Complaints place the Eon and Impax drugs squarely within the relinquished subject matter.

Accordingly, the Court finds that any reasonable litigant confronting the facts Plaintiffs have alleged at the time the infringement suits were filed would have concluded that GSK would be estopped from claiming infringement by equivalence. Without a viable argument for infringement by equivalence, GSK could not reasonably have expected success on the merits. Thus, for the purposes of this Motion to Dismiss, GSK's infringement actions against Eon and Impax must be considered objectively baseless.

C. *The Effect of GSK's Limited Success in the Eon Suit*

GSK also argues that regardless of whether the underlying infringement suits are objectively baseless under the facts Plaintiffs have alleged, the success GSK enjoyed in the Eon action precludes a finding that the infringement suits were objectively baseless. In effect, GSK is asking the Court to adopt a *per se* rule that any action which achieves a certain "measure of success"-in this case, surviving summary judgment motion and securing a preliminary injunction-is, as a matter of law, *not* "objectively baseless."

***11** To be sure, several courts appear to have adopted the rule GSK is proposing. *See, e.g., Twin City Bakery Workers & Welfare Fund v. Astra Aktiebolag*, 207 F.Supp.2d 221, 224 (S.D.N.Y.2002) (summary judgment denied and claims found not baseless because claims went unchallenged until trial); *Harris v. Custom Builkders, Inc. v. Hoffmeyer*, 834 F.Supp. 256, 261-62 (N.D.Ill.1993) (finding that an "action that is well enough grounded, factually and legally, to survive a motion for summary judgment is sufficiently meritorious to lead a reasonable litigant to conclude that they had some chance of success on the merits.")

However, the controlling authority is the Federal Circuit, whose decisions govern "all antitrust claims premised on the bringing of a patent infringement suit." *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1069 (Fed.Cir.1998). Thus, it is to the Federal Circuit that the Court must look for guidance as to the merits of GSK's proposed *per se* rule, and the Federal Circuit has explicitly rejected it. In *Filmtec Corp. v. Hydranautics,* the panel held that the "court hearing the antitrust claim must make its own assessment of the objective merits of the predicate suit," regardless of how the case fared before the previous court. 67 F.3d 931, 937 (Fed.Cir.1995) (quoting *Boulware v. Nevada Dep't of Human Resources*, 960 F.2d 793, 799 (9th Cir.1992)). Thus, "preliminary success on the merits does not necessarily preclude a court from concluding that litigation was baseless." *Id.* at 938. *See also In re Relafen Antitrust Lit.*, 346 F.Supp.2d 349, 362-65 (D.Mass.2004) (holding that a plaintiff's surviving summary judgment does not prove as a matter of law that his case was not objectively baseless).

Furthermore, the *per se* rule GSK proposes is inconsistent with *Professional Real Estate,* where the Court made clear that the "objectively baseless" determination depends on the reasonable expectations of the party alleged to have brought the frivolous suit. By employing the language of "expectations" the Court was indicating that the analysis should focus on what the litigant knew or reasonably could have known *at the time the suits were filed, not* on the res-

ults of the suits. *Professional Real Estate*, 508 U.S. at 61 n. 5. The analysis, in other words, must be prospective not retrospective, and therefore should be limited to the law and the facts as they existed when the decision to file suit was made. *Id.* at 67 (Souter, J., concurring) (stating that the standard is whether "on the undisputed facts and the law as it stood when Columbia filed its suit, a reasonable litigant could realistically have expected success on the merits."). Accordingly, the Court rejects GSK's proposed *per se* rule that the success it enjoyed in the Eon case precludes a finding that the action was objectively baseless.

D. *Conclusion*

***12** Accepting the allegations of the Complaints as true, which the Court must do at this stage of the proceedings, GSK's Motion to Dismiss based on *Noerr-Pennington* immunity will be denied.

IV. THE WALKER PROCESS CLAIMS

The Saj Complaint claims an additional violation of the Sherman Act based on GSK's allegedly fraudulent prosecution of patent '994 (*"Walker Process* claim"). *See Walker Process Equip., Inc. v. Food Mach. And Chem. Corp.*, 382 U.S. 172, 174, 86 S.Ct. 347, 15 L.Ed.2d 247 (1965) ("[T]he enforcement of a patent procured by fraud on the Patent Office may be violative of § 2 of the Sherman Act provided the other elements necessary to a § 2 are present."). GSK argues that that claim should be dismissed (1) because the Saj Complaint failed to plead the alleged fraud with the requisite particularity; and (2) for lack of standing.

Rule 9(b) requires that "in all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity. Malice, intent, knowledge, and other condition of mind of a person may be averred generally." Fed.R.Civ.P. 9(b). In the Third Circuit, a plaintiff's complaint must set out the circumstances of the fraud with enough particularity to "place the defendants on notice of the precise misconduct with which they are charged, and to safeguard defendants against spurious charges of immoral behavior." *Seville Indus. Mach. Corp. v. Southmost Mach. Corp.*, 742 F.2d 786, 791 (3d Cir.1984); *In re: Rockefeller Ctr. Prop., Inc. Sec. Litig.*, 311 F.3d 198, 216 (3d Cir.2002). While providing allegations of "date, place or time" is one means of giving the defendant adequate notice, it is not exclusive. "Plaintiffs are free to use alternative means of injecting precision and some measure of substantiation into their allegations of fraud." *Id.*

At oral argument, the Saj Plaintiffs conceded that in its current state, the Walker Process claim did not satisfy the requirements of Fed.R.Civ.P. 9(b). Accordingly, that claim will be dismissed without prejudice.

V. INJUNCTIVE RELIEF

The Medical Mutual and Sheet Metal Complaints do not seek damages for GSK's alleged violations of the Sherman Act, but only injunctive relief under § 16 of the Clayton Antitrust Act. They request that the Court enjoin Defendants from "engaging in future anticompetitive practices concerning the manufacture, distribution or sale of Wellbutrin SR and Zyban." *See* Medical Mutual Complaint ¶ 99; Sheet Metal Complaint ¶ 131.

GSK argues that these claims should be dismissed because the Complaints fail to allege an antitrust injury cognizable under § 16 the Clayton Act. The Court agrees. "In order to seek injunctive relief under § 16 [of the Clayton Act], a private plaintiff must allege *threatened loss or damage* 'of the type the antitrust laws were designed to prevent and that flows from that which makes defendants' acts unlawful." ' *Cargill, Inc. v. Monfort of Colorado, Inc.*, 479 U.S. 104, 113, 107 S.Ct. 484, 93 L.Ed.2d 427 (1986) (quoting *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489, 97 S.Ct. 690, 50 L.Ed.2d 701 (1977)) (emphasis added). Now that all the infringement suits have terminated in the generic companies' favor, there is no unlawful conduct to be enjoined. Accordingly, the Court finds that the Medical Mutual and Sheet Metal Plaintiffs have failed to allege a claim cognizable under § 16 of the Clayton Act. *See In re Relafen Antitrust Lit.*, 221 F.R.D. 260, 274 (D.Mass.2004) (holding that antitrust plaintiffs were not entitled to injunctive relief for antitrust claim based on frivolous lawsuits where the suits had

already been resolved since "it is difficult to imagine how [the alleged] violation might recur.").

VI. CONCLUSION

***13** For the foregoing reasons, the Court will grant GSK's Motion to Dismiss with respect to the Walker Process Claims in the Saj Complaint and the claims under § 16 of the Clayton Act in the Sheet Metal and Medical Mutual Complaints, all without prejudice.FN9 With respect to the remaining claims, GSK's Motion will be denied.

> FN9. Plaintiffs should generally be given an opportunity to amend claims dismissed pursuant to a 12(b)(6) motion unless such amendment would be "inequitable, futile, or untimely." *Alston v. Parker*, 363 F.3d 229, 236 (3d Cir.2004).

ORDER

AND NOW, this 9th day of March, 2006, upon consideration of Defendants' Motion to Dismiss (docket no. 23 in 04-Cv-5525, docket no. 8 in 04-Cv-5898, docket no. 16 in 05-Cv-396) and the responses thereto and for the reasons stated in the accompanying memorandum, it is ORDERED that the Motion is GRANTED in part and DENIED in part. It is FURTHER ORDERED that

(1) The Walker Process claim in the Saj Complaint (04-5525) is DISMISSED WITHOUT PREJUDICE.
(2) Count one in the Sheet Metal Complaint (04-5898) is DISMISSED WITHOUT PREJUDICE.
(3) Count one in the Medical Mutual Complaint (05-396) is DISMISSED WITHOUT PREJUDICE.
(4) GSK's Motion to Dismiss is DENIED as to all other counts.

E.D.Pa.,2006.
In re Wellbutrin SR Antitrust Litigation
Not Reported in F.Supp.2d, 2006 WL 616292 (E.D.Pa.), 2006-1 Trade Cases P 75,158

Briefs and Other Related Documents (Back to top)

- 2006 WL 1760263 (Trial Pleading) Defendant's Answer to Plaintiffs' Consolidated and Amended Class Action Complaint (May 19, 2006) Original Image of this Document (PDF)
- 2006 WL 1760270 (Trial Pleading) Defendants' Answer to Plaintiffs' Class Action Complaint (May 19, 2006) Original Image of this Document (PDF)
- 2006 WL 1765476 (Trial Pleading) Defendants' Answer to Plaintiff's Original Complaint (May 19, 2006) Original Image of this Document (PDF)
- 2006 WL 1760262 (Trial Motion, Memorandum and Affidavit) Defendant Glaxosmithkline's Reply Memorandum of Law in Support of its Motion to Certify Order for Interlocutory Appeal and for Stay of Proceedings (May 2, 2006) Original Image of this Document (PDF)
- 2006 WL 1760269 (Trial Motion, Memorandum and Affidavit) Defendant Glaxosmithkline's Reply Memorandum of Law in Support of its Motion to Certify Order for Interlocutory Appeal and for Stay of Proceedings (May 2, 2006) Original Image of this Document (PDF)
- 2006 WL 1765472 (Trial Motion, Memorandum and Affidavit) Defendant Glaxosmithkline's Reply Memorandum of Law in Support of Its Motion to Certify Order for Interlocutory Appeal and for Stay of Proceedings (May 2, 2006) Original Image of this Document (PDF)
- 2006 WL 1358151 (Trial Motion, Memorandum and Affidavit) Plaintiff Medical Mutual of Ohio's Memorandum in Opposition to Defendant's GlaxoSmithKline's Motion to Certify Order for Interlocutory Appeal and for Stay of Proceedings (Apr. 18, 2006) Original Image of this Document (PDF)
- 2006 WL 1358213 (Trial Motion, Memorandum and Affidavit) Direct Purchaser Plaintiffs' Memorandum in Opposition to Defendant GlaxoSmithKline's Motion to Certify Order for Interlocutory Appeal and for Stay of Proceedings (Apr. 13, 2006) Original Image of this Document (PDF)
- 2006 WL 1354840 (Trial Pleading) Consolidated and Amended Class Action Complaint (Apr. 6, 2006) Original Image of this Document (PDF)
- 2:05cv00396 (Docket) (Jan. 28, 2005)
- 2:04cv05898 (Docket) (Dec. 17, 2004)
- 2:04cv05525 (Docket) (Nov. 30, 2004)
- 2004 WL 3122728 (Trial Pleading) Class Action Complaint (2004) Original Image of this Document (PDF)

END OF DOCUMENT

EXHIBIT G

H

Briefs and Other Related Documents

Brotech Corp. v. White Eagle Intern. Technologies Group, Inc.E.D.Pa.,2003.

United States District Court,E.D. Pennsylvania.

BROTECH CORPORATION and Purolite International, Ltd.

v.

WHITE EAGLE INTERNATIONAL TECHNOLOGIES GROUP, INC., et al.

No. Civ.A. 03-232.

Filed Jan. 16, 2003.

Nov. 18, 2003.

represented by Bruce Bellingham, Bruce L. Thall, Spector Gadon & Rosen PC, Phila, PA, Lead Attorney, Attorney to be Noticed, David M. Beckwith, Mauricio A. Flores, McDermot, Will & Emery, Irvine, CA, Lead Attorney, Attorney to be Noticed, Paul R. Rosen, Spector Gadon & Rosen, P.C., Philadelphia, PA, Lead Attorney, Attorney to be Noticed, Raphael V. Lupo, McDermott, Will & Emery, Washington, DC, Lead Attorney, Attorney to be Noticed, for Brotech Corporation, Plaintiff.

represented by Bruce Bellingham, Bruce L. Thall, Paul R. Rosen, (See above for address), Lead Attorney, Attorney to be Noticed, for Purolite International, Ltd., Plaintiff.

represented by Jeffrey A. Schwab, Abelman Frayne & Schwab, New York, NY, Lead Attorney, Attorney to be Noticed, Peter Michael Ryan, Phila, PA, Lead Attorney, Attorney to be Noticed, Richard L. Crisona, Abelman Frayne & Schwab, New York, NY, Lead Attorney, Attorney to be Noticed, for White Eagle International Technologies Group, Inc., Defendant.

represented by Jeffrey A. Schwab, Peter Michael Ryan, Richard L. Crisona, (See above for address), Lead Attorney, Attorney to be Noticed, for White Eagle International Technologies, L.P., Defendant.

represented by Jeffrey A. Schwab, Peter Michael Ryan, Richard L. Crisona, (See above for address), Lead Attorney, Attorney to be Noticed, for Renaltech International, LLC, Defendant.

represented by Jeffrey A. Schwab, (See above for address), Lead Attorney, Attorney to be Noticed, for Renaltech International, LLC, Counter Claimant.

represented by Jeffrey A. Schwab, (See above for address), Lead Attorney, Attorney to be Noticed, for White Eagle International Technologies Group, Inc., Counter Claimant.

represented by Jeffrey A. Schwab, (See above for address), Lead Attorney, Attorney to be Noticed, for White Eagle International Technologies, L.P., Counter Claimant.

represented by David M. Beckwith, Mauricio A. Flores, Raphael V. Lupo, (See above for address), Lead Attorney, Attorney to be Noticed, for Brotech Corporation, Counter Defendant.

MEMORANDUM

PADOVA, J.

*1 Before the Court is Plaintiffs Brotech Corporation's and Purolite International, Ltd.'s Motion to Dismiss Defendant RenalTech International, LLC's Counterclaim. For the reasons that follow, the Motion is granted and the Counterclaim is dismissed in its entirety, without prejudice.

I. BACKGROUND

Plaintiffs have brought this action to correct the name of the inventor on patents relating to inventions of certain Russian scientists and for equitable title to those patents, misappropriation of trade secrets, tortious interference with contract and other common law claims arising from Defendants' alleged interference with the relationship between Plaintiffs and those Russian scientists. The Amended Complaint alleges that, for the last ten years, Plaintiffs' employees have engaged in a cooperative research and development program with several Russian scientists led by Professor Vadim A. Davankov of the Russian Academy of Science. (Am.Compl.¶ 2.) As a result of that research, Plaintiffs' employees and the Russian scientists have developed unique macronet and micronet copolymer resins for a variety of adsorpitve uses and methods to produce these resins in a commercially viable manner, including their use in renal dialysis. (Am.Compl.¶ 4.) The Amended Complaint further alleges that Defendants procured eleven

United States patents on these inventions, misrepresenting their ownership and failing to acknowledge Plaintiffs' property rights. (Am.Compl.¶ 73-74.) The disputed patents are: U.S. Patent 5,773,384 issued June 30, 1998; U.S. Patent 5,904,663 issued May 18, 1999; U.S. Patent 6,087,300 issued July 11, 2000; U.S. Patent 6,114,466 issued September 5, 2000; U.S. Patent 6,127,311 issued October 3, 2000; U.S. Patent 6,133,393 issued October 17, 2000; U.S. Patent 6,136,424 issued October 24, 2000; U.S. Patent 6,153,707 issued November 28, 2000; U.S. Patent 6,156,851 issued December 5, 2000; U.S. Patent 6,159,377 issued December 12, 2000; U.S. Patent 6,303,702 issued October 16, 2001. (Am.Compl. ¶ 74.)

Defendant RenalTech International, LLC ("RenalTech") has asserted counterclaims against both Plaintiffs asserting that Plaintiffs are using their superior economic resources and this litigation to gain control of Defendants' pioneering technology. The Counterclaim alleges that RenalTech is developing new technology to assist chronic renal failure patients by removing middle molecular weight toxins, which are not efficiently removed by renal dialysis, from the blood. (Countercl.¶¶ 15-16.) RenalTech's chemists have developed this technology, a biocompatible adsorbent polymer and a device incorporating this polymer, trademarked BetaSorb, which has been designed to be used in conjunction with hemodialysis. (Countercl.¶ 16.) A human clinical trial of BetaSorb is currently underway in the United States. (Countercl.¶ 17.) RenalTech is also studying the use of its polymer technology to treat severe sepsis. (Countercl.¶¶ 23-24.) RenalTech claims to be the only organization currently conducting human clinical trials for such products. (Countercl.¶ 32.)

***2** The Counterclaim alleges that Plaintiffs have brought this action in order to coerce RenalTech into ceding control of its intellectual property to Plaintiffs so that Plaintiffs can unlawfully monopolize the market for its products. (Countercl.¶ 33.) The Counterclaim alleges claims against Plaintiffs for attempted monopolization pursuant to Section 2 of the Sherman Act, 15 U.S.C. § 2; conspiracy to restrain trade pursuant to Section 1 of the Sherman Act, 15 U.S.C. § 1; and for tortious interference with existing and prospective business relations. Plaintiffs have moved to dismiss the Counterclaim.

II. LEGAL STANDARD

When determining a Motion to Dismiss pursuant to Rule 12(b)(6), the court must accept as true all well pleaded facts in the complaint, or counter-claim, and any reasonable inferences derived from those facts, and view them in the light most favorable to the Plaintiff. *FTC v. Commonwealth Marketing Group, Inc.*, 72 F.Supp.2d 530, 535 (W.D.Pa.1999) (citations omitted). However, the Court need not accept "bald assertions or legal conclusions." *Morse v. Lower Merion School District*, 132 F.3d 902, 906 (3d Cir.1997). The dismissal standard is higher in antitrust cases than generally. *Rolite, Inc. v. Wheelabrator Envir. Systems, Inc.*, 958 F.Supp. 992, 995 (E.D.Pa.1997). However, the facts underlying the elements of an antitrust claim must be pled with specificity. *Syncsort Incorporated v. Sequential Software, Inc.*, 50 F.Supp.2d 318, 328 (D.N.J.1999) (dismissing antitrust counterclaim brought pursuant to Section 2 of the Sherman Act for failure to allege specific facts setting forth the elements of a claim for monopolization or attempted monopolization); *see also Com. of Pennsylvania ex. rel. Zimmerman v. PepsiCo., Inc.*, 836 F.2d 173, 182 (3d Cir.1988) ("When the requisite elements are lacking, the costs of modern federal antitrust litigation and the increasing caseload of the federal courts counsel against sending the parties into discovery when there is no reasonable likelihood that the plaintiffs can construct a claim from the events related in the complaint.") (quoting *Car Carriers, Inc. v. Ford Motor Co.*, 734 F.2d 1101, 1106 (7th Cir.1984)).

III. DISCUSSION

A. *The Antitrust Claims*

RenalTech's first two claims for relief allege antitrust claims arising from the filing of the instant lawsuit. The Counterclaim alleges that Plaintiffs have brought the instant litigation in "an undisguised effort to coerce RenalTech into ceding control of the core of its intellectual property to BroTech and Purolite International so that they can unlawfully monopolize the

market ... BroTech and Purolite International ... are seeking to exploit their vastly superior economic resources to pressure RenalTech through the intimidation of this sham lawsuit." (Countercl.¶ 33.) Plaintiffs have moved to dismiss these claims for relief on the grounds that they are immune from Sherman Act liability based upon the filing of this action pursuant to the *Noerr-Pennington* doctrine. Plaintiffs also maintain that, if their claim of immunity is denied, RenalTech's Sherman Act claims should be dismissed for failure to state a claim upon which relief may be granted pursuant to Rule 12(b)(6).

1. *The Noerr-Pennington Doctrine*

***3** In *Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 135-36 (1961), the United States Supreme Court recognized that the Sherman Act does not restrain "attempts to influence the passage or enforcement of laws" and does not "prohibit two or more persons from associating together in an attempt to persuade the legislature or the executive to take particular action with respect to a law that would produce a restraint or a monopoly." In *United Mine Workers of America v. Pennington*, 381 U.S. 657, 670 (1965), the Supreme Court noted that "Noerr shields from the Sherman Act a concerted effort to influence public officials regardless of intent of purpose." In *California Motor Transport Co. v. Trucking Unlimited*, 404 U.S. 508 (1972), the Supreme Court extended the *Noerr-Pennington* doctrine to the right to access the courts, but noted that the filing of sham litigation would not be immune from suit under the Sherman Act:

it would be destructive of rights of association and of petition to hold that groups with common interests may not, without violating the antitrust laws, use the channels and procedures of state and federal agencies and courts to advocate their causes and points of view respecting resolution of their business and economic interests vis-a-vis their competitors.

We said, however, in Noerr that there may be instances where the alleged conspiracy "is a mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor and the application of the Sherman Act would be justified."

Id. at 510-11 (citing *Noerr*, 365 U.S. at 144). In *Professional Real Estate Investors, Inc. v. Columbia Picture Industries, Inc.*, 508 U.S. 49 (1993), the Supreme Court examined what constitutes sham litigation and determined that anti-competitive intent does not turn a protected lawsuit into a sham proceeding open to attack under the Sherman Act, stating that "an objectively reasonable effort to litigate cannot be sham regardless of subjective intent." *Id.* at 56-57. The Supreme Court emphasized that the objective reasonableness of a lawsuit is not affected by the anti-competitive purpose of the litigant. *Id.* at 59 ("Our decisions therefore establish that the legality of objectively reasonable petitioning 'directed toward obtaining governmental action' is 'not at all affected by any anticompetitive purpose [the actor] may have had.' ") (quoting *Noerr*, 365 U.S. at 140). The Supreme Court also defined sham litigation:We now outline a two-part definition of "sham" litigation. First, the lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits. If an objective litigant could conclude that the suit is reasonably calculated to elicit a favorable outcome, the suit is immunized under *Noerr*, and an antitrust claim premised on the sham exception must fail. Only if challenged litigation is objectively meritless may a court examine the litigant's subjective motivation. Under this second part of our definition of sham, the court should focus on whether the baseless lawsuit conceals "an attempt to interfere directly with the business relationships of a competitor," *Noerr, supra*, 365 U.S., at 144 81 S.Ct., at 533 (emphasis added), through the "use [of] the governmental *process*-as opposed to the *outcome* of that process-as an anticompetitive weapon," *Omni*, 499 U.S., at 380, 111 S.Ct., at 1354 (emphasis in original). This two-tiered process requires the plaintiff to disprove the challenged lawsuit's *legal* viability before the court will entertain evidence of the suit's *economic* viability. Of course, even a plaintiff who defeats the defendant's claim to *Noerr* immunity by demonstrating both the objective and the subjective components of a sham must still prove a substantive antitrust violation. Proof of a sham merely deprives the defendant of immunity; it does not relieve the plaintiff of the obligation to establish all other elements of his claim.

*4 *Id.* at 60-61 (emphasis in original, footnote omitted). The Supreme Court further explained that, if a party had probable cause to file a lawsuit, it is not sham litigation. *Id.* at 62 ("The existence of probable cause to institute legal proceedings precludes a finding that an antitrust defendant has engaged in sham litigation .")

Plaintiffs argue that, since the Amended Complaint survived Defendants' Motion to Dismiss, they had probable cause to bring this lawsuit and they are immune from antitrust liability pursuant to *Professional Real Estate Investors.* RenalTech maintains that the denial of Defendants' Motion is not dispositive because, when deciding the Motion to Dismiss, the Court accepted all of the allegations of the Amended Complaint as true. RenalTech contends that the factual allegations underlying Plaintiffs' claims will be found to be objectively baseless and, therefore, will not support the application of *Noerr-Pennington* immunity. RenalTech further argues that its claims for relief brought pursuant to the Sherman Act allege the elements of "sham" litigation set forth in *Professional Real Estate Investors* and, therefore, Plaintiffs' Motion to Dismiss its claims for relief pursuant to the Sherman Act should be denied. The Counterclaim alleges that: Plaintiffs' claims in this action are objectively baseless (Countercl.¶¶ 5, 34); Plaintiffs motivation in filing suit was not to obtain a judgment, but to pressure RenalTech into ceding control of its intellectual property in a coerced settlement (Countercl.¶¶ 6, 36); Plaintiffs' claims are "an undisguised effort to coerce RenalTech into ceding control of the core of its intellectual property to [Plaintiffs] so that they can unlawfully monopolize the market" (Countercl.¶ 33); and, this is a sham lawsuit (Countercl.¶¶ 33, 35). The Court finds that RenalTech has alleged that the instant lawsuit is "sham" litigation pursuant to the definition set forth in Professional Real Estate Investors, 508 U.S. at 60-61. The Court further finds that it cannot determine, on the record of this Motion to Dismiss, that Plaintiffs had probable cause to file the Amended Complaint. Accordingly, Plaintiffs' Motion to Dismiss RenalTech's Sherman Act claims based upon the *Noerr-Pennington* doctrine is denied.

2. *Attempted monopolization*

RenalTech's first claim for relief alleges a claim for attempted monopolization in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2. In order to state a claim for attempted monopolization in violation of Section 2 of the Sherman Act, RenalTech must allege the following elements:
(1) that the defendant has engaged in predatory or anticompetitive conduct with (2) a specific intent to monopolize and (3) a dangerous probability of achieving monopoly power. In order to determine whether there is a dangerous probability of monopolization, courts have found it necessary to consider the relevant market and the defendant's ability to lessen or destroy competition in that market.

***5** Spectrum Sports, Inc. v. McQuillan, 506 U.S. 447, 456 (1993) (citations omitted). Plaintiffs argue that this claim must be dismissed because the Counterclaim does not adequately plead the relevant product market. The United States Court of Appeals for the Third Circuit ("Third Circuit") has recognized that the failure to plead the relevant product market is a sufficient basis for dismissal of an antitrust claim. Queen City Pizza v. Domino's Pizza, Inc., 124 F.3d 430, 436 (3d Cir.1997); *see also,* Syncsort, 50 F.Supp.2d at 331. The Third Circuit stated the elements of the product market as follows:"The outer boundaries of a product market are determined by the reasonable interchangeability of use or the cross-elasticity of demand between the product itself and substitutes for it." Where the plaintiff fails to define its proposed relevant market with reference to the rule of reasonable interchangeability and cross-elasticity of demand, or alleges a proposed relevant market that clearly does not encompass all interchangeable substitute products even when all factual inferences are granted in plaintiff's favor, the relevant market is legally insufficient and a motion to dismiss may be granted.

Id. (quoting Brown Shoe Co. v. U.S., 370 U.S. 294, 325, (1962); Tunis Bros. Co., Inc. v. Ford Motor Co., 952 F.2d 715, 722 (3d Cir.1991)). The Third Circuit noted that the "outer boundaries of a relevant market are determined by reasonable interchangeability of use," *id.* at 437 (citations omitted), and defined cross-elasticity as "a measure of the substitutability of products from the point of view of buyers," i.e., the

measure of "the responsiveness of the demand for one product to changes in the price of a different product." *Id.* at 438 n. 6 (citation omitted).

The Counterclaim defines the relevant product market as follows: "hemocompatible or biocompatible polymeric resins designed to remove middle molecular weight compounds or toxins from physiological fluids, including human blood." (Countercl.¶ 31.) The Court finds that RenalTech has failed to define the relevant product market with reference to the rule of reasonable interchangeability of use or cross-elasticity of demand. The Court further finds that the Counterclaim alleges a proposed market which does not encompass any interchangeable substitute products and does not allege that there are no substitute products. Accordingly, Plaintiffs' Motion to Dismiss RenalTech's claim for relief pursuant to Section 2 of the Sherman Act is granted pursuant to Rule 12(b)(6).

3. *Conspiracy to Restrain Trade*

RenalTech's second claim for relief alleges a claim for conspiracy to restrain trade pursuant to Section 1 of the Sherman Act, 15 U.S.C. § 1. In order to state a claim under Section 1 of the Sherman Act, the claimant must plead the following elements:
(1) concerted action by the defendants; (2) that produced anticompetitive effects within the relevant product and geographic markets; (3) that the objects of the conduct pursuant to the concerted action were illegal; and (4) that it was injured as a proximate result of the concerted action.

***6** *Petruzzi's IGA v. Darling-Delaware*, 998 F.2d 1224, 1229 (3d Cir.1993). Plaintiffs assert four grounds for dismissal of this claim: (1) that the instant action was not brought for an anticompetitive purpose; (2) that, as affiliated corporations, they cannot act in concert for antitrust purposes; (3) that the Counterclaim does not plead the relevant product market; and (4), that the Counterclaim does not allege an antitrust injury.

Plaintiffs argue that their claims for relief are actually pro-competitive, rather than anticompetitive, because they seek to share the patents at issue in this suit with Defendants. (Pls. Mem. at 26.) However, Plaintiffs' argument is belied by the Amended Complaint, which seeks a declaration that Plaintiffs are the exclusive owners of the patents at issue. (Am.Compl.¶¶ 80-84.) As exclusive ownership of these patents would give Plaintiffs a legal monopoly over the disputed inventions, the Court cannot find, for purposes of this Motion to Dismiss, that Plaintiffs' claims for relief are pro-competitive.

Plaintiffs also argue that, as affiliated corporations, they are so interrelated that their actions are deemed unilateral and not concerted for antitrust purposes. Plaintiffs rely on *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752 (1984). In *Copperweld,* the Supreme Court founmd that a corporation and its wholly owned subsidiary could not conspire with each other for purposes of liability under Section 1 of the Sherman Act:
A parent and its wholly owned subsidiary have a complete unity of interest. Their objectives are common, not disparate; their general corporate actions are guided or determined not by two separate corporate consciousnesses, but one.... If a parent and a wholly owned subsidiary do "agree" to a course of action, there is no sudden joining of economic resources that had previously served different interests, and there is no justification for § 1 scrutiny....
[I]n reality a parent and a wholly owned subsidiary *always* have a "unity of purpose or a common design." They share a common purpose whether or not the parent keeps a tight rein over the subsidiary; the parent may assert full control at any moment if the subsidiary fails to act in the parent's best interests.

Id. at 771-72 (emphasis in original). The Third Circuit has recognized that two subsidiaries of the same corporation are similarly incapable of conspiring with each other for the purposes of Section 1. *Siegel Transfer, Inc. v. Carrier Exp., Inc.*, 54 F.3d 1125, 1133 (3d Cir.1995) (citing *Advanced Health-Care Services, Inc. v. Radford Community Hosp.*, 910 F.2d 139, 146 (4th Cir.1990)).

The pleadings which comprise the record on this Motion to Dismiss do not, however, describe the corporate relationship between the Plaintiffs sufficiently to allow the Court to determine, at this stage of the litig-

ation, that Plaintiffs are affiliated corporations incapable of conspiring to violate the antitrust laws. The Amended Complaint does not allege that Plaintiffs are subsidiaries of the same parent corporation. The Amended Complaint describes Plaintiffs as follows:

*7 9. Plaintiff BroTech Corporation is a Delaware Corporation that trades under the name "The Purolite Company." It is headquartered at 150 Monument Road, Bala Cynwyd, PA 19004. BroTech is responsible for the exclusive marketing in North America, and elsewhere, of the products of Purolite International, Ltd. It also performs manufacturing operations for Purolite International, Ltd.

10. Plaintiff Purolite International, Ltd., is a corporation organized under the laws of the United Kingdom. It is headquartered at Cowbridge Road, Pontyclun, Wales, where it develops, manufactures and markets macronet and micronet copolymer resins.

(Am.Compl.¶¶ 9-10.) The Counterclaim alleges that the "Purolite Company" consists of "at least BroTech and Purolite International," but does not state whether those corporations are wholly, or majority, owned subsidiaries of the Purolite Company. (Countercl.¶ 12.) Moreover, Plaintiffs took the position, in response to Defendants' Motion to Dismiss the Amended Complaint, that they are not corporate affiliates. (Pls.' Mem. in Opp. to Defs.' Mot. to Dismiss at 7 n. 1.) The Court cannot, therefore, find, on this Motion to Dismiss, that Plaintiffs are incapable of conspiring with each other for purposes of Section 1 of the Sherman Act. Indeed, the doctrine of judicial estoppel may prevent Plaintiffs from taking the position, in this proceeding, that they are affiliated corporations, since they relied on the fact that they are not affiliated in their response to Defendants' Motion to Dismiss. *See* *Krystal Cadillac-Oldsmobile GMC Truck, Inc. v. General Motors Corp.*, 337 F.3d 314, 319 (3d Cir.2003) (" '[t]he basic principle of judicial estoppel ... is that absent any good explanation, a party should not be allowed to gain an advantage by litigation on one theory, and then seek an inconsistent advantage by pursuing an incompatible theory." ') (citing *Ryan Operations G.P. v. Santiam-Midwest Lumber Co.*, 81 F.3d 355, 358 (3d Cir.1996)).

Plaintiffs also argue that RenalTech's claim for relief pursuant to Section 1 of the Sherman Act should be denied for failure to allege antitrust injury and for failure to adequately allege the product market. In order to recover damages in an antitrust suit, a private plaintiff must prove the existence of an antitrust injury, "injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful." *Atlantic Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 334 (1990) (citing *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977)). The Third Circuit has recognized that, because the purpose of the antitrust laws is to protect competition, the court must examine "the antitrust injury question from the viewpoint of the consumer. 'An antitrust plaintiff must prove that challenged conduct affected the prices, quantity or quality of goods or services,' not just his own welfare." *Mathews v. Lancaster General Hosp.*, 87 F.3d 624, 641 (3d Cir.1996) (quoting *Tunis Bros.*, 952 F.2d at 728). RenalTech alleges that it was injured as follows:

*8 37. And although they have not yet succeeded, BroTech's and Purolite International's predatory litigation tactics are having their intended effect. The pendency of the lawsuit has been raised by RenalTech's investors and potential investors, it has diverted management time and attention, it has consumed scarce financial resources, and has been the subject of discussion with RenalTech's major commercial partner, Fresenius. Thus, RenalTech has already been damaged, and is threatened with still greater damage if BroTech and Purolite International are not called to account for their predatory, vexatious conduct.

(Am.Compl.¶ 37.) The Court finds that the Counterclaim does not allege an antitrust injury. As the Court has also found that the Counterclaim does not sufficiently allege the relevant product market, Plaintiffs' Motion to Dismiss RenalTech's claim for relief pursuant to Section 1 of the Sherman Act is granted pursuant to Rule 12(b)(6).

B. *The Tortious Interference Claims*

RenalTech's third and fourth claims for relief allege that, by filing the instant lawsuit, Plaintiffs deliberately interfered with RenalTech's current business relations (third claim for relief) and prospective business relations (fourth claim for relief). In order to es-

tablish tortious interference with existing contractual, or business, relations,[FN1] a claim must allege the following elements:

> FN1. Although RenalTech suggests that New York law might apply to its claims for tortious interference, it states that New York and Pennsylvania law do not differ with respect to these claims. The elements of claims for tortious interference with existing and prospective business relations under Pennsylvania law are identical to the elements of claims for tortious interference with existing and prospective contractual relations, and are based on Sections 766 and 766B of the Restatement (Second) of Torts. *See* Thompson Coal Co. v. Pike Coal Co., 412 A.2d 466, 470-71 (Pa.1979). The elements of claims for tortious interference with existing and prospective business relations under New York law are also based on Sections 766 and 766B of the Restatement (Second) of Torts. *See* Kunica v. St. Jean Financial, Inc., Civ.A.No. 97 Civ. 3804(RWS), 1998 WL 437153, at *7 (S.D.N.Y. Aug. 3, 1998); *Scutti Enterprises, LLC v. Park Place Entertainment Corp.*, 322 F.3d 211, 215 (2d Cir.2003) (noting that, if the business relations at issue do not involve a valid contract, the claim is treated as one falling under Section 766B of the Restatement (Second) of Torts). As the laws of Pennsylvania and New York are the same with respect to these claims, the Court need not engage in a choice of law analysis with regard to this issue. *Oil Shipping, B.V. v. Denizcilik*, 10 F.3d 1015, 1018 (3d Cir.1993) (noting that a choice of law analysis is only necessary where an actual conflict between two bodies of law exists.)

(1) existence of contract; (2) purposeful action by the defendant specifically intended to harm the existing relation; (3) absence of privilege or justification on the part of the defendant; and (4) occasioning of actual legal damage as a result of defendant's conduct. *CAT Internet Services Inc. v. Magazines.com, Inc.*, No.Civ.A. 00-2135, 2001 WL 8858, at *5 n. 1 (E.D.Pa. Jan. 4, 2001). In order to prove intentional interference with prospective contractual, or business, relations, a claim must allege the following elements: (1) existence of a prospective contractual relation; (2) purpose or intent by defendant to harm plaintiff by preventing the relationship from occurring; (3) absence of privilege or justification on the part of the actor (appellee); and (4) the occurrence of actual harm or damage to plaintiff as a result of the actor's conduct.

Id. at *4 (citing *Glen v. Point Park College*, 441 Pa. 474, 272 A.2d 895, 898 (Pa.1971)).

Plaintiffs argue that Renaltech's claims for tortious interference with existing and prospective business relations must be dismissed because the filing of the lawsuit in this action was absolutely privileged. Plaintiffs rely on the principle of judicial privilege, which immunizes communications issued in the regular course of judicial proceedings which are "pertinent and material to the redress or relief sought." *Post v. Mendel*, 507 A.2d 351, 356 (Pa.1986). However, the Third Circuit has determined that the filing of a lawsuit without probable cause and "for a purpose other than the securing of redress from the court" is not immunized by the judicial privilege. *Silver v. Mendel*, 894 F.2d 598, 603-05 (3d Cir.1990) (finding that the Supreme Court of Pennsylvania would conclude that the judicial privilege did not bar a claim for tortious interference with contract based on allegations that "defendants caused an involuntary petition in bankruptcy to be filed without probable cause to believe in the merit of the petition and for a purpose other than the securing of redress from the court."). The Counterclaim alleges that the instant lawsuit is a sham (Countercl.¶¶ 33, 35); that the claims in this action are objectively baseless (Countercl.¶¶ 5, 34); and that Plaintiffs did not file suit for the purpose of obtaining a judgment. (Countercl.¶¶ 6, 36.) Accepting these allegations as true, the Court cannot find, for purposes of this Motion to Dismiss, that the filing of the instant lawsuit was privileged.

***9** Plaintiffs also argue that RenalTech's claims for tortious interference with existing and prospective business relations should be denied for failure to al-

lege any existing or prospective contract with which Plaintiffs interfered or any actual harm or damage arising from Plaintiffs' conduct. The Pennsylvania courts do not recognize a claim for tortious interference with existing or prospective contractual, or business, relations in which the "interference was directed toward the plaintiff, rather than toward a third party." *Allen v. The Washington Hospital*, 34 F.Supp.2d 958, 965 (E.D.Pa.1999).

The Pennsylvania Courts have adopted Section 766 of the Restatement (Second) of Torts, which sets out the cause of action for tortious interference with existing contractual, or business, relations:
One who intentionally and improperly interferes with the performance of a contract (except a contract to marry) between another and a third person by inducing or otherwise causing the third person not to perform the contract, is subject to liability to the other for the pecuniary loss resulting to the other from the third person's failure to perform the contract.

Nathanson v. Medical College of Pennsylvania, 926 F.2d 1368, 1388 (3d Cir.1991) (citing *Adler, Barish, Daniels, Levin and Creskoff v. Epstein*, 393 A.2d 1175, 1181-83 (Pa.1978). The Pennsylvania Courts have not, however, adopted Section 766A of the Restatement (Second) of Torts, which addresses interference directed at the plaintiff, rather than at the third party:One who intentionally and improperly interferes with the performance of a contract ... between another and a third person, by preventing the other from performing the contract or causing his performance to be more expensive or burdensome, is subject to liability to the other for the pecuniary loss resulting to him.

Gemini Physical Therapy and Rehabilitation, Inc. v. State Farm Mut. Auto. Ins. Co., 40 F.3d 63, 66 (3d Cir.1994) (citing Section 766A of the Restatement (Second) of Torts). The Counterclaim does not allege that Plaintiffs' filing of the instant lawsuit caused any third party not to perform an existing contract with RenalTech or that RenalTech lost actual pecuniary benefits from such a contract with a third party. *See Shiner v. Moriarty*, 706 A.2d 1228, 1238-39 (Pa.Super.Ct.1998) (recognizing that, to maintain an action for intentional interference with contractual relations, a party must allege "lost pecuniary benefits flowing from the contract itself.") (citing *Pelagatti v. Cohen*, 536 A.2d 1337, 1343-44 (Pa.Super.Ct.1987)).FN2 The Court finds, accordingly, that the Counterclaim does not state a claim for tortious interference with existing business relations upon which relief may be granted.FN3

> FN2. The New York courts also require a party claiming tortious interference with business relations to establish pecuniary injury from the loss of its contract with the third party. *H.L. Hayden Co. of New York, Inc. v. Siemens Medical Systems, Inc.*, 879 F.2d 1005, 1024 (2d Cir.1989).
>
> FN3. The Court would reach the same result under New York law, as the New York courts also have not adopted Section 766A of the Restatement (Second) of Torts, or suggested that they would be inclined to do so. *D'Andrea v. Rafla-Demetrious*, 146 F.3d 63, 66 (2d Cir.1998) (affirming grant of summary judgment to Defendant where plaintiff claimed that "the defendant interfered with performance of the *plaintiff's* own contractual obligations.") (emphasis in original).

The tort of tortious interference with prospective contractual, or business, relations is set forth in Section 766B of the Restatement (Second) of Torts:
[o]ne who intentionally and improperly interferes with another's prospective contractual relation ... is subject to liability to the other for the pecuniary harm resulting from the loss of the benefits of the relation, whether the interference consists of (a) inducing or otherwise causing a third person not to enter into or continue the prospective relation or (b) preventing the other from acquiring or continuing the prospective relation.

***10** Restatement (Second) of Torts, § 766B. The Pennsylvania Courts have not adopted Section 766(B)(b). *Allen*, 34 F.Supp.2d at 964-65; *Leopold Graphics, Inc. v. The CIT Group/Equipment Financing, Inc.*, No.Civ.A. 01-cv-6028, 2002 WL 1397449, at *5 (E.D. Pa. June 26, 2002). Consequently, there is

no cause of action for interference with prospective contractual relations where the interference is directed at the plaintiff, rather than at a third party. *Coram Healthcare Corp. v. Aetna U.S. Healthcare, Inc.*, No.Civ.A. 99-3330, 2000 WL 217750, at *4 (E.D.Pa. Feb. 26, 2000).[FN4] As the interference alleged in the Counterclaim was directed at RenalTech, rather than at a third party, the Court finds that the Counterclaim does not state a claim for tortious interference with prospective business relations upon which relief may be granted.

FN4. Defendant does not suggest that the New York courts have adopted Section 766B(b) of the Restatement (Second) of Torts. The Court has found no authority holding that the New York courts have adopted this section.

IV. CONCLUSION

For the foregoing reasons, the Court finds that the Counterclaim fails to state a claim upon which relief may be granted pursuant to either Section 1 or Section 2 of the Sherman Act or for tortious interference with either existing or prospective business relations. Accordingly, Plaintiffs' Motion to Dismiss is granted without prejudice. An appropriate order follows.

ORDER

AND NOW, this 18th day of November, 2003, upon consideration of Plaintiffs' Motion to Dismiss Defendants' Counter-Claims (Docket No. 28), Defendant RenalTech's response thereto, and the argument held in open court on October 2, 2003, IT IS HEREBY ORDERED that the Motion is GRANTED without prejudice and with leave to file an amended counterclaim within twenty (20) days of the date of this Order.

E.D.Pa.,2003.
Brotech Corp. v. White Eagle Intern. Technologies Group, Inc.
Not Reported in F.Supp.2d, 2003 WL 22797730 (E.D.Pa.), 2003-2 Trade Cases P 74,221

Briefs and Other Related Documents (Back to top)

- 2005 WL 2849083 (Trial Motion, Memorandum and Affidavit) Plaintiffs' Opposition to Defendants' Motion to Strike Jury Trial Demand (Sep. 26, 2005) Original Image of this Document (PDF)
- 2005 WL 2849082 (Trial Motion, Memorandum and Affidavit) Plaintiffs' Answer to Defendants' Motion to Introduce Prior Felony Convictions (Sep. 21, 2005) Original Image of this Document (PDF)
- 2005 WL 2849081 (Trial Motion, Memorandum and Affidavit) Plaintiffs' Answer in Opposition to Defendants' Motion to Preclude Extrinsic Evidence and Limit the Scope of Testimony About Andrew Braverman's Past Conduct (Sep. 20, 2005) Original Image of this Document (PDF)
- 2005 WL 2849080 (Trial Motion, Memorandum and Affidavit) Plaintiffs' Opposition to Defendants' Motion in Limine No. 4 to Strike the Expert Report and Preclude the Testimony of John W. Dewhirst (Sep. 19, 2005) Original Image of this Document (PDF)
- 2005 WL 2849079 (Trial Motion, Memorandum and Affidavit) MOTION TO STRIKE PLAINTIFFS' JURY TRIAL DEMAND (Sep. 16, 2005) Original Image of this Document (PDF)
- 2005 WL 2849076 (Trial Motion, Memorandum and Affidavit) Defendants' Motion in Limine No. 1 to Preclude Extrinsic Evidence and Limit the Scope of Questions About Witness Andrew Braverman's Past Conduct (Sep. 12, 2005) Original Image of this Document (PDF)
- 2005 WL 2849077 (Trial Motion, Memorandum and Affidavit) Defendants' Memorandum in Opposition to the Motion of Plaintiffs for a Separate Trial on Their State Law Claims (Sep. 12, 2005) Original Image of this Document (PDF)
- 2005 WL 2849078 (Trial Motion, Memorandum and Affidavit) Defendants' Motion in Limine No. 2 to Introduce Prior Felony Convictions of Donald Brodie, Stefan Brodie and Brotech for Impeachment of Donald and Stefan Brodie's Credibility (Sep. 12, 2005) Original Image of this Document (PDF)
- 2005 WL 2682869 (Trial Motion, Memorandum and Affidavit) Motion for Summary Judgment Dismissing this Action (Aug. 12, 2005) Original Image of this Document (PDF)
- 2004 WL 2718242 (Trial Motion, Memorandum and Affidavit) Plaintiffs' Answer to Defendants' Mo-

tion to Compel Certain Redeposition Testimony of Stefan Brodie (Sep. 17, 2004) Original Image of this Document with Appendix (PDF)

• 2004 WL 2718234 (Trial Motion, Memorandum and Affidavit) Defendants' Motion to Compel Certain Deposition Testimony of Stefan Brodie (Sep. 3, 2004) Original Image of this Document with Appendix (PDF)

• 2004 WL 2718226 (Trial Motion, Memorandum and Affidavit) Response of Plaintiffs to Defendants' Motion for Entry of Amended Pretrial Scheduling Order (Aug. 27, 2004) Original Image of this Document with Appendix (PDF)

• 2004 WL 2718216 (Trial Motion, Memorandum and Affidavit) Reply Memorandum of Plaintiffs in Support of their Motion for an Order Compellilng Discovery of Laboratory Notebooks of Russian Scientists and for their Depositions (Aug. 19, 2004) Original Image of this Document with Appendix (PDF)

• 2004 WL 2718221 (Trial Motion, Memorandum and Affidavit) Plaintiffs' Reply Memorandum in Support of Their Motion for an Order Compelling Defendants' Production of Polymer and Specifications (Aug. 19, 2004) Original Image of this Document (PDF)

• 2004 WL 2718171 (Trial Motion, Memorandum and Affidavit) Defendants' Opposition to Plaintiff's Motion for an Order Compelling Discovery of Braverman Documents, Renaltech Minutes and Agendas, and Antitrust Documents, and a Rule 30(b)(6) Deposition (Aug. 16, 2004) Original Image of this Document with Appendix (PDF)

• 2004 WL 2718178 (Trial Motion, Memorandum and Affidavit) Defendants' Opposition to Plaintiffs' Motion for an Order Compelling Discovery of Laboratory Notebooks of Russian Scientists and for Their Redepositions (Aug. 16, 2004) Original Image of this Document with Appendix (PDF)

• 2004 WL 2718189 (Trial Motion, Memorandum and Affidavit) Defendants' Opposition to Plaintiffs' Motion for an Order Compelling Defendants' Production of Polymer and Specifications (Aug. 16, 2004) Original Image of this Document with Appendix (PDF)

• 2004 WL 2718162 (Trial Pleading) Answer to Third Third Amended Complaint (Aug. 6, 2004) Original Image of this Document (PDF)

• 2004 WL 2718154 (Trial Motion, Memorandum and Affidavit) Plaintiffs' Motion for an Order Compelling Discovery of Laboratory Notebooks of Russian Scientists and for Their Redepositions (Jul. 16, 2004) Original Image of this Document (PDF)

• 2004 WL 2718150 (Trial Motion, Memorandum and Affidavit) Motion of Plaintiffs for an Order Compelling Discovery of Braverman Documents, Renaltech Minutes and Agendas, and Antitrust Documents, and a Rule 30(b)(6) Deposition (Jul. 15, 2004) Original Image of this Document with Appendix (PDF)

• 2004 WL 2718146 (Trial Pleading) Answer to Second Amended Complaint (Mar. 25, 2004) Original Image of this Document (PDF)

• 2004 WL 2718142 (Trial Motion, Memorandum and Affidavit) Plaintiffs' Supplemental Memorandum in Support of Their Motion to Dismiss Defendants' Amended Counterclaims (Mar. 22, 2004) Original Image of this Document (PDF)

• 2004 WL 2718137 (Trial Motion, Memorandum and Affidavit) Defendants' Supplemental Memorandum in Opposition to Plaintiffs' Motion to Dismiss Defendants' Amended Counterclaims (Mar. 18, 2004) Original Image of this Document (PDF)

• 2004 WL 2718133 (Trial Pleading) Second Amended Complaint (Mar. 10, 2004) Original Image of this Document (PDF)

• 2003 WL 23905571 (Trial Motion, Memorandum and Affidavit) Defendants' Memorandum in Opposition to Plaintiffs' Motion to Dismiss Defendants' Amended Counterclaims (Dec. 31, 2003) Original Image of this Document (PDF)

• 2003 WL 23905550 (Trial Motion, Memorandum and Affidavit) Plaintiffs' Motion To Dismiss Defendants' Amended Counterclaim (Dec. 15, 2003) Original Image of this Document with Appendix (PDF)

• 2003 WL 23905531 (Trial Pleading) Amended Counterclaim (Dec. 8, 2003) Original Image of this Document (PDF)

• 2003 WL 23905512 (Trial Motion, Memorandum and Affidavit) Memorandum In Support of Plaintiffs' Motion To Execute Requests For Letters Rogatory And Hague Convention Discovery (Sep. 15, 2003) Original Image of this Document (PDF)

• 2003 WL 23905494 (Trial Motion, Memorandum and Affidavit) Defendants' Memorandum In Opposi-

tion to Plaintiffs' Motion to Dismiss Defendants' Counter-Claims (Aug. 14, 2003) Original Image of this Document (PDF)

• 2003 WL 23905473 (Trial Motion, Memorandum and Affidavit) Plaintiffs' Motion to Dismiss Defendants' Counter-Claims (Jul. 28, 2003) Original Image of this Document (PDF)

• 2003 WL 23905453 (Trial Pleading) Answer and Counterclaim (Jul. 14, 2003) Original Image of this Document (PDF)

• 2003 WL 23905437 (Trial Motion, Memorandum and Affidavit) Defendants' Reply Memorandum In Support of Their Motion To Dismiss The Amended Complaint Under Fed. R. Civ. P. 12(b)(6) (Jun. 13, 2003) Original Image of this Document (PDF)

• 2003 WL 23905417 (Trial Motion, Memorandum and Affidavit) Plaintiffs' Memorandum of Law in Opposition to Defendants' Rule 12(b)(6) Motion to Dismiss Complaint (May 30, 2003) Original Image of this Document (PDF)

• 2003 WL 23905394 (Trial Motion, Memorandum and Affidavit) Defendants' Memorandum In Support of Their Motion To Dismiss The Amended Complaint Under Fed. R. Civ. P. 12(b)(6) (Apr. 11, 2003) Original Image of this Document (PDF)

• 2003 WL 23905373 (Trial Pleading) Amended Complaint (Mar. 10, 2003) Original Image of this Document (PDF)

• 2003 WL 23905348 (Trial Pleading) Complaint for Declaratory Judgment (Jan. 16, 2003) Original Image of this Document (PDF)

• 2:03cv00232 (Docket) (Jan. 16, 2003)

• 2003 WL 23905676 (Trial Motion, Memorandum and Affidavit) Reply Memorandum of Purolite in Support of Its Motion for an Order Compelling Discovery of Braverman Documents, Renaltech Minutes, Agendas and Antitrust Documents, Together with a Rule 30(b)(6) Deposition (2003) Original Image of this Document with Appendix (PDF)

END OF DOCUMENT